

Sandostatin® LAR Depot (octreotide acetate) Injection and Sandostatin® (octreotide acetate) Injection



When requesting Sandostatin® LAR Depot (octreotide acetate) or Sandostatin® (octreotide acetate), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved indications^{1,2}

- Treatment of acromegaly
- Treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.
- Treatment of the profuse watery diarrhea associated with vasoactive intestinal peptide secreting tumors.

Approved Off-label Compensial use⁴

- No off-label uses meet evidence standards*

*Oncology-related off-label uses are addressed in the Medical Oncology program.

Coverage Guidelines

Acromegaly

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

- Clinical evidence of acromegaly (e.g., frontal bossing, coarse facial features, thick lips, protruding jaw with widely spaced teeth, large hands and feet, etc.)³
- The individual has a high pretreatment IGF-1 level for age and/or gender³
- The individual is not a candidate for pituitary surgery or has had surgery that was not curative^{1,2,3}

For reauthorization:

- Must meet above criteria and must show IGF-1 level has decreased or normalized while on therapy^{1,2,3}

Carcinoid Tumors

The individual has severe diarrhea and flushing episodes secondary to metastatic carcinoid tumors.^{1,2}

Vasoactive Intestinal Peptide Tumors

The individual has profuse watery diarrhea secondary to vasoactive intestinal peptide secreting tumors^{1,2}

Approval duration: 12 months

Additional Information for Prescribers^{1,2}

Our prescribers are alerted to the following safety concerns as educational points/reminders:

- Gallbladder abnormalities may occur. Monitor periodically.
- Hypoglycemia or hyperglycemia may occur. Glucose monitoring is recommended and antidiabetic treatment may need adjustment.
- Hypothyroidism may occur. Monitor thyroid levels periodically.
- Monitoring of vitamin B12 levels is recommended during therapy.
- Individuals on total parenteral nutrition (TPN) should have periodic monitoring of zinc levels.
- Drugs mainly metabolized by CYP3A4 and which have a narrow therapeutic index (e.g., quinidine, terfenadine) should be monitored appropriately.
- Bradycardia, arrhythmia, or conduction abnormalities may occur. Use with caution in at-risk individuals.

References

1. Sandostatin® (octreotide) prescribing information. Stein, Switzerland: Novartis Pharma; March 2012. Accessed April 3, 2017. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/sandostatin_inj.pdf
2. Sandostatin® LAR prescribing information. Basle, Switzerland: Novartis Pharma; July 2016 Accessed April 3, 2017. https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/sandostatin_lar.pdf
3. Katzmeyer L, Atkinson J, Cook D, et al. American Association of Endocrinologists Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Acromegaly. *Endocrine Practice*. 2011;17:4. Accessed February 21, 2017. <https://www.aace.com/files/acromegaly-guidelines.pdf>
4. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed February 21, 2017. <https://www.micromedexsolutions.com>

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