Octreotide Agents

Override(s)	Approval Duration
Prior Authorization	1 year
Quantity Limit	

Medications	Quantity Limit
Sandostatin (octreotide acetate)	May be subject to quantity limit
Sandostatin LAR Depot (octreotide acetate) 10mg, 30mg Kit	
Sandostatin LAR Depot (octreotide acetate) 20mg Kit	

APPROVAL CRITERIA

Requests for Sandostatin or Sandostatin LAR Depot (octreotide) may be approved if the following criteria are met:

- I. Individual has a diagnosis of acromegaly; AND
- II. Diagnosis of acromegaly has been confirmed by, or in consultation with, a board-certified endocrinologist who has reviewed and verified the test results (including but not limited to: Insulin-like Growth Factor 1 levels; Oral Glucose Tolerance Test with associated Growth Hormone (GH) levels) that are indicative of a positive test; **AND**
- III. Individual has had an inadequate response to any of the following:
 - A. Surgical resection; **OR**
 - B. Pituitary irradiation; **OR**
 - C. Bromocriptine mesylate at maximally tolerated doses;

OR

IV. Surgery and/or radiotherapy is not an option;

OR

V. Individual has a diagnosis of carcinoid tumors and is using for any of the following: Metastatic carcinoid tumors to suppress or inhibit severe diarrhea and flushing episodes associated with the disease:

OR

- VI. Individual has a diagnosis of neuroendocrine and adrenal tumors and is using for any of the following:
 - A. For the management of unresectable locoregional disease or distant metastasis (NCCN 2A); **OR**

- B. For the treatment of the profuse watery diarrhea associated with VIPomas; **OR**
- C. Prophylactic treatment prior to surgery for gastrinoma (AHFS);

OR

- VII. Individual is using for bleeding Gastroesophageal (GE) varices and the following criteria are met:
 - A. GE varices are associated with liver disease (Banares 2002, Corley 2001); AND
 - B. Octreotide acetate is used in combination with endoscopic therapy or alone if endoscopic therapy is not immediately available (Garcia-Tsao 2007);

OR

VIII. Individual is using for malignant bowel obstruction to manage gastrointestinal (GI) symptoms (e.g. nausea, pain, or vomiting) (Berger 2016);

OR

IX. Individual is using for thymic carcinoma or thymoma with or without prednisone (NCCN 2A);

OR

- X. Individual is requesting Sandostatin LAR for meningiomas in central nervous system cancers (NCCN 2A); **AND**
 - A. Individual has surgically inaccessible recurrent or progressive disease when radiation is not possible; **AND**
 - B. Individual is using in combination with everolimus;

OR

XI. Individual is requesting Sandostatin for rapid relief of symptoms or for breakthrough symptoms in individuals taking long-acting octreotide acetate when any of the criteria are met for the above uses (NCCN 2A).

Requests for Sandostatin or Sandostatin LAR Depot (octreotide) may **not** be approved for any of the following:

- I. Individual is using for the treatment of chylothorax; **OR**
- II. Individual is using for the treatment of diarrhea associated with acquired immunodeficiency syndrome; **OR**
- III. Individual is using for the treatment of gastrointestinal diseases(e.g. bleeding from vascular malformations, gastroparesis, pancreatitis, prevention of postoperative complications following pancreatic surgery, short bowel syndrome, or upper GI bleeding); **OR**
- IV. Individual is using for the treatment of Graves' ophthalmopathy; **OR**
- V. Individual is using for the treatment of hypothalamic obesity; **OR**

- VI. Individual is using for the treatment of other carcinomas (e.g. advanced breast cancer, hepatocellular cancer, or prostate cancer); **OR**
- VII. Individual is using for the treatment of polycystic kidney disease; **OR**
- VIII. When the above criteria are not met and for all other indications.

Key References:

- 1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 25, 2024.
- 2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
- 4. NCCN Drugs & Biologics Compendium (NCCN Compendium[™]) © 2024 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.
- 5. Archimandritis A, Tsirantonaki M, Tryphonos M, et al. Ranitidine versus ranitidine plus octreotide in the treatment of acute non-variceal upper gastrointestinal bleeding: a prospective randomised study. Curr Med Res Opin. 2000; 16(3):178-183.
- 6. Bajetta E, Procopio G, Ferrari L, et al. A randomized, multicenter prospective trial assessing long-acting release octreotide pamoate plus tamoxifen as a first line therapy for advanced breast carcinoma. Cancer. 2002; 94(2):299-304.
- 7. Banares R, Albillos A, Rincon D, et al. Endoscopic treatment versus endoscopic plus pharmacologic treatment for acute variceal bleeding: a meta-analysis. Hepatology. 2002; 35(3):609-615.
- 8. Berger J, Lester P, Rodrigues L. Medical Therapy of Malignant Bowel Obstruction With Octreotide, Dexamethasone, and Metoclopramide. Am J Hosp Palliat Care. 2016 May;33(4):407-410. Accessed: June 25, 2024.
- 9. Broder MS, Chang E, Cherepanov D, Neary MP, Ludlam WH. INCIDENCE AND PREVALENCE OF ACROMEGALY IN THE UNITED STATES: A CLAIMSBASED ANALYSIS. Endocr Pract. 2016; 22: 1327-1335.
- 10. Brown C, Subramanian V, Wilcox CM, Peter S. Somatostatin analogues in the treatment of recurrent bleeding from gastrointestinal vascular malformations: an overview and systematic review of prospective observational studies. Dig Dis Sci. 2010; 55(8):2129-2134.
- Caroli A, Perico N, Perna A, et al. Effect of longacting somatostatin analogue on kidney and cyst growth in autosomal dominant polycystic kidney disease (ALADIN): a randomised, placebo-controlled, multicentre trial. Lancet. 2013; 382(9903):1485-1495.
- 12. Chapman JA, Costantino JP, Dong B, et al. Octreotide LAR and tamoxifen versus tamoxifen in phase III randomize early breast cancer trials: NCIC CTG MA.14 and NSABP B-29. Breast Cancer Res Treat. 2015; 153(2):353-360.
- 13. Corley DA, Cello JP, Adkisson W, et al. Octreotide for acute esophageal variceal bleeding: a meta-analysis. Gastroenterology. 2001; 120(4):946-954.
- 14. Das A, Shah PS. Octreotide for the treatment of chylothorax in neonates. Cochrane Database Syst Rev. 2010;(9):CD006388.
- 15. Edmunds MC, Chen JD, Soykan I, et al. Effect of octreotide on gastric and small bowel motility in patients with gastroparesis. Aliment Pharmacol Ther. 1998; 12(2):167-174.
- 16. Friedlander TW, Weinberg VK, Small EJ, et al. Effect of the somatostatin analog octreotide acetate on circulating insulin-like growth factor-1 and related peptides in patients with non-metastatic castration-resistant prostate cancer: results of a phase II study. Urol Oncol. 2012; 30(4):408-414.
- 17. Fujita T, Daiko H. Efficacy and predictor of octreotide treatment for postoperative chylothorax after thoracic esophagectomy. World J Surg. 2014; 38(8):2039-2045.
- 18. Garcia-Tsao G, Sanyal AJ, Grace ND, et al. Prevention and management of gastroesophageal varices and variceal hemorrhage in cirrhosis. Am J Gastroenterol. 2007; 102(9):2086-2102.
- 19. Hogan MC, Masyuk TV, Page LJ, et al. Randomized clinical trial of long-acting somatostatin for autosomal dominant polycystic kidney and liver disease. J Am Soc Nephrol. 2010; 21(6):1052-1061
- 20. Ismail NA, Gordon J, Dunning J. The use of octreotide in the treatment of chylothorax following cardiothoracic surgery. Interact Cardiovasc Thorac Surg. 2015; 20(6):848-854.
- 21. Jia WD, Zhang CH, Xu GL, et al. Octreotide therapy for hepatocellular carcinoma: a systemic review of the evidence from randomized controlled trials. Hepatogastroenterology. 2010; 57(98):292-299.
- 22. unquera F, Saperas E, Videla S, et al. Long-term efficacy of octreotide in the prevention of recurrent bleeding from gastrointestinal angiodysplasia. Am J Gastroenterol. 2007; 102(2):254-260.
- 23. Loyaga-Rendon RY, Hashim T, Tallaj JA, et al. Octreotide in the management of recurrent gastrointestinal bleed in patients supported by continuous flow left ventricular assist devices. ASAIO J. 2015; 61(1):107-109.
- 24. Lustig RH, Hinds PS, Ringwald-Smith K, et al. Octreotide therapy of pediatric hypothalamic obesity: a double-blind, placebo-controlled trial. J Clin Endocrinol Metab. 2003; 88(6):2586-2592.
- 25. Nehra V, Camilleri M, Burton D, et al. An open trial of octreotide long-acting release in the management of short bowel syndrome. Am J Gastroenterol. 2001; 96(5):1494-1498.

- 26. Nikou GC, Toumpanakis C, Katsiari C, et al. Treatment of small intestinal disease in systemic sclerosis with octreotide: a prospective study in seven patients. J Clin Rheumatol. 2007; 13(3):119-123.
- 27. Panel on opportunistic infections in HIV-infected adults and adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Last updated May 29, 2018. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf.
- 28. Ruggenenti P, Remuzzi A, Ondei P, et al. Safety and efficacy of long-acting somatostatin treatment in autosomal-dominant polycystic kidney disease. Kidney Int. 2005; 68(1):206-216.
- 29. Soudah HC, Hasler WL, Owyang C. Effect of octreotide on intestinal motility and bacterial overgrowth in scleroderma. N Engl J Med. 1991; 325(21):1461-1467.
- 30. Stan MN, Garrity JA, Bradley EA, et al. Randomized, double-blind, placebo-controlled trial of long-acting release octreotide for treatment of Graves' ophthalmopathy. J Clin Endocrinol Metab. 2006; 91(12):4817-4824.
- 31. Swanson MS, Hudson RL, Bhandari N, et al. Use of octreotide for the management of chyle fistula following neck dissection. JAMA Otolaryngol Head Neck Surg. 2015; 141(8):723-727.
- 32. Szilagyi A, Ghali MP. Pharmacological therapy of vascular malformations of the gastrointestinal tract. Can J Gastroenterol. 2006; 20(3):171-178.
- 33. Testoni D, Hornik CP, Neely ML, et al. Best Pharmaceuticals for Children Act Pediatric Trials Network Administrative Core Committee. Safety of octreotide in hospitalized infants. Early Hum Dev. 2015; 91(7):387-392.
- 34. Verne GN, Eaker EY, Hardy E, Sninsky CA. Effect of octreotide and erythromycin on idiopathic and sclerodermaassociated intestinal pseudoobstruction. Dig Dis Sci. 1995; 40(9):1892-1901.
- 35. Xu W, Zhou YF, Xia SH. Octreotide for primary moderate to severe acute pancreatitis: a meta-analysis. Hepatogastroenterology. 2013; 60(126):1504-1508.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.