JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP069
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Octreotide Acetate Injectable Products: Sandostatin, Sandostatin LAR Depot, Bynfezia Pen, generic octreotide acetate**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Bynfezia, octreotide acetate, sandostatin, sandostatin LAR Depot,

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I. POLICY

A. Injectable Octreotide Acetate Products (Sandostatin, Sandostatin LAR Depot, Bynfezia Pen, and generic octreotide acetate) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Sandostatin, Sandostatin LAR Depot, Bynfezia Pen, and generic octreotide acetate may be approved for patients who meet thefollowing:
   1. Acromegaly
      a. Documentation has been submitted showing the following:
         I. Patient has a diagnosis of acromegaly
         II. Patient has a high pretreatment IGF-1 level for age and/or gender based on the laboratory report reference range
         III. Patient had an inadequate or partial response to surgery or radiotherapy, or there is a clinical reason why the member has not had surgery or radiotherapy
   2. Neuroendocrine tumors (NETs)
      a. Tumors of the gastrointestinal (GI) tract
         I. Documentation has been submitted showing the patient has a diagnosis of locoregional advanced or metastatic NETs of the GI tract or unresected primary gastrinoma
      b. Tumors of the thymus
         I. Documentation has been submitted showing the patient has a diagnosis of unresectable or metastatic NETs of the thymus
      c. Tumors of the lung
         I. Documentation has been submitted showing the patient has a diagnosis of unresectable or metastatic NETs of the lung
      d. Tumors of the pancreas
         I. Documentation has been submitted showing the patient has a diagnosis of NETs of the pancreas
   3. Carcinoid syndrome

a. Documentation has been submitted showing that the requested octreotide acetate product will be used for treatment of carcinoid syndrome in one of the following clinical situations:
   I. Monotherapy
   II. Combination with telotristat for persistent diarrhea due to poorly controlled carcinoid syndrome
   III. Combination with other systemic therapy options for persistent symptoms such as flushing or diarrhea, or for progressive disease

4. Vasoactive intestinal peptide tumors (VIPomas)
   a. Documentation has been submitted showing the requested octreotide acetate product will be used for management of symptoms related to hormone hypersecretion of VIPomas
5. Pheochromocytoma and paraganglioma
   a. Documentation has been submitted showing the patient has a diagnosis of locally unresectable or metastatic pheochromocytoma and paraganglioma
6. Thymomas and thymic carcinomas
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of thymoma or thymic carcinoma
      II. The requested octreotide acetate product will be used as a second-line therapy with or without prednisone for one of the following:
         • Unresectable disease following first-line chemotherapy for potentially resectable locally advanced disease, solitary metastasis, or ipsilateral pleural metastasis
         • Extrathoracic metastatic disease
7. AIDS-associated diarrhea
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of AIDS-associated severe secretory diarrhea
      II. Patient has had trial and inadequate response with one of the following:
         • anti-microbial (e.g., ciprofloxacin or metronidazole)
         • anti-motility agents (e.g., loperamide or diphenoxylate and atropine)
8. Bowel obstruction in terminal cancer
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of terminal cancer
      II. The requested octreotide acetate product will be used for management of GI symptoms (e.g., nausea, pain, vomiting) of inoperable bowel obstruction
9. Chemotherapy- and radiation-induced diarrhea
   a. Documentation has been submitted showing the following:
      I. Patient has a diagnosis of chemotherapy-or radiation-induced diarrhea
      II. Patient meets one of the following:
         • Receiving treatment with chemotherapy or radiation
         • Has grade 3 or greater diarrhea according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE)
10. Enterocutaneous fistula
    a. Documentation has been submitted showing that the requested octreotide acetate product will be used for management of volume depletion from enterocutaneous fistula
11. Gastroesophageal varices
    a. Documentation has been submitted showing that the requested octreotide acetate product will be used for treatment of acute bleeding of gastroesophageal varices associated with cirrhosis

12. Islet cell tumors
    a. Documentation has been submitted showing the following:
    b. Patient has been diagnosed with functioning islet cell tumors (e.g., insulinomas or glucagonomas)
    c. The requested octreotide acetate product will be used for stabilization of blood glucose levels
13. Pancreatic fistulas
    a. Documentation has been submitted showing that the requested octreotide acetate product will be used for prevention and treatment of pancreatic fistulas following pancreatic surgery
14. Pituitary adenoma
    a. Documentation has been submitted showing the patient has a diagnosis of pituitary adenoma
15. Short bowel syndrome
    a. Documentation has been submitted showing the following:
        I. Patient has a diagnosis of short bowel syndrome
        II. Patient has a daily intravenous fluid requirement of greater than 3 liters
16. Zollinger-Ellison syndrome
    a. Documentation has been submitted showing the patient has a diagnosis of Zollinger-Ellison syndrome

B. Sandostatin and generic octreotide acetate may be approved for patients who meet the following:
1. Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia
    a. Documentation has been submitted showing the following:
        I. Patient is an infant
        II. Patient has a diagnosis of CHI and persistent hyperinsulinemic hypoglycemia

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
1. Caveats: Initial approval will be limited to 6 months of therapy for CHI and persistent hyperinsulinemic hypoglycemia, Gastroesophageal varices, and Pancreatic fistulas

B. Continuation of therapy will be based on indication:
1. Acromegaly:
    a. Continuation may be provided in 12-month intervals with documentation that the patient's IGF-1 level has decreased or normalized since starting treatment
2. Carcinoid syndrome, VIPomas, AIDS-associated diarrhea, bowel obstruction, chemotherapy/radiation-induced diarrhea, islet cell tumors, and Zollinger-Ellison syndrome:
    a. Continuation may be provided in 12-month intervals with documentation that the patient has experienced clinical benefit from treatment, evidenced by improvement or stabilization in clinical signs and symptoms
3. Neuroendocrine tumors (NETs), Pheochromocytoma and paraganglioma, Thymomas and thymic carcinomas, Enterocutaneous fistula, Gastroesophageal varices, Pancreatic fistulas, Pituitary adenoma, Short bowel syndrome, and CHI/persistent hyperinsulinemic hypoglycemia:
    a. Continuation may be provided in the same duration interval as the initial approval with evidence that the patient still meets the initial criteria noted above

IV. EXCLUSIONS

A. Octreotide acetate products will not be covered for the following:
1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/ HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, octreotide, depot form for intramuscular injection, 1 mg	J3253
Injection, octreotide, non-depot form for subcutaneous or intravenous injection, 25 mcg	J3254

VII. REFERENCES

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VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

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