JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP059
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Somutaline Depot**	*Revision Date*	04/20/2022
		Page	1 of 3

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Somutaline Depot

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**2**
IV.	**EXCLUSIONS**	**2**
V.	**RECOMMENDED DOSAGE**	**2**
VI.	**CODES**	**2**
VII.	**REFERENCES**	**2**
VIII.	**APPROVALS**	**3**

I. POLICY

A. Somatuline Depot (lanreotide) 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. Somatuline Depot may be approved for patients who meet the following:
   1. Acromegaly
      a. Documentation has been submitted showing:
         I. Patient has a high pretreatment IGF-1 level for age and/or gender supported by laboratory report results
         II. And one of the following:
            - Patient has had inadequate response to radiotherapy or surgery
            - A clinical reason has been provided as to why the patient has not had surgery or radiotherapy
   2. Neuroendocrine tumors (NETs)
      a. Documentation has been submitted showing at least one of the following diagnoses:
         I. locoregional advanced or metastatic NETs of the GI tract or unresected primary gastrinoma
         II. unresectable or metastatic of NETs of the thymus
         III. unresectable or metastatic NETs of the lung
         IV. NETs of the pancreas.
   3. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
      a. Documentation has been submitted showing the patient has unresectable, well- or moderatelydifferentiated, locally advanced or metastatic GEP-NETs.
   4. Carcinoid syndrome
      a. Documentation has been submitted supporting the patient has carcinoid syndrome and that Somatuline Deport will be used as one of the following
         I. Monotherapy treatment
         II. In combination therapy with other systemic treatments for persistent symptoms, such as flushing or diarrhea, or for progressive disease
         III. In combination therapy with telotristat for persistent diarrhea due to poorly controlled disease

5. Pheochromocytoma and paraganglioma
   a. Documentation has been submitted showing the patient has locally unresectable or metastatic pheochromocytoma and paraganglioma.
6. Zollinger-Ellison syndrome
   a. Documentation has been submitted showing the patient has Zollinger-Ellison syndrome.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing a beneficial response to treatment:
   1. Additionally, diagnosis-specific requirements:
      a. Acromegaly: Documentation has been submitted showing the patient's IGF-level has been reduced or normalized while on treatment
      b. Carcinoid syndrome and Zolinger-Ellison syndrome: Documentation has been submitted showing the patient has experienced a clinical improvement, or stabilization of signs and symptoms as a result of treatment.

IV. EXCLUSIONS

A. Somatuline Depot 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 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, lanreotide, 1 mg	J1930

VII. REFERENCES

1. Somatuline Depot [prescribing information]. Basking Ridge, NJ: Ipsen Biopharmaceuticals, Inc.; April 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org. Accessed March 1,2022.

3. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99:3933-3951.
4. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. Endocr Pract. 2011;17(suppl 4):1-44.
5. Caplin ME, Pavel M, Cwikla JB, et al. Lanreotide in metastatic enteropancreatic neuroendocrine tumors. N Engl J Med. 2014;371:224-233.

VIII. APPROVALS

Signature on file at JHHC

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

Review Dates: 04/20/2022

Revision Dates: