	uisiana thcare actions		
Clinical Policy: Lanreotide (Somatuline Depot and Unbranded)	_	Formatted: Font: Arial Narrow	
Reference Number: LA.PHAR.391		Formatted: Font: Bold	
Effective Date: <u>04.28.21</u>			
	g Implications		
	Revision Log		
See Important Reminder at the end of this policy for important regulatory and le information.	egal		
<b>Description</b> Lanreotide (Somatuline <sup>®</sup> Depot) isand unbranded lanreotide are a somatostatin anal	log.		
<ul> <li>FDA Approved Indication(s)</li> <li>Somatuline Depot isand unbranded lanreotide are indicated for:</li> <li>Long-term treatment of acromegalic patients who have had an inadequate resport cannot be treated with surgery and/or radiotherapy</li> <li>Treatment of adult patients with unresectable, well- or moderately-differentiated advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NE improve progression-free survival</li> </ul>	d, locally		
<ul> <li>Somatuline Depot is additionally indicated for:</li> <li>Treatment of adults with carcinoid syndrome; when used, it reduces the frequen acting somatostatin analog rescue therapy</li> </ul>	acy of short-		
<ul> <li>Treatment of adults with carcinoid syndrome; when used, it reduces the frequen acting somatostatin analog rescue therapy</li> <li>Policy/Criteria Provider must submit documentation (such as office chart notes, lab results or otherap)</li> </ul>			
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nreotide		
6.7. Dose does not exceed 120 mg every 4 weeks.		Formatted: Font: Bold
Approval duration:	_	
6 months		
	_	Formatted: Font: Bold
B. Carcinoid Syndrome (must meet all):		Formatted: Font: Bold
1. Diagnosis of carcinoid syndrome (associated with NETs of the gastrointestinal tract,	-	Formatted: Font: Bold
lung, and thymus, otherwise known as carcinoid tumors);		
2. Prescribed by or in consultation with an oncologist;		
3. Age $\geq$ 18 years;		
4. Request is for either Somatuline Depot or unbranded lanreotide;		
4.5. Request meets one of the following (a or b):*		
a. Dose does not exceed 120 mg every 4 weeks;		
b. Dose is supported by practice guidelines or peer-reviewed literature for the		
relevant off-label use (prescriber must submit supporting evidence).		
*Prescribed regimen must be FDA-approved or recommended by NCCN		
Approval duration: 6 months		
C. Neuroendocrine Tumors (must meet all):	_	Formatted: Font: Bold
1. Diagnosis of one of the following (a, b, <del>c, or dc</del> ):	$\sim$	Formatted: Font: Bold
a. GEP-NET (see Appendix D for tumor types);), and:		
i. If insulinoma, disease is somatostatin receptor (SSTR)positive;	-	Formatted: Indent: Left: 1", Hanging: 0.25", Pattern: C
b. Pheochromocytoma or paraganglioma (adrenal NETs);	*	(Background 1)
c. One of the following NETs which is SSTR-positive or has hormonal symptoms (i	i.	Formatted: Pattern: Clear (Background 1)
ii, or iii):	.,	
i. Thymic NET;		Formatted: Indent: Left: 1", Hanging: 0.25", Pattern: C
ii. Bronchopulmonary NET;		(Background 1)
iii. Grade 3 NET with favorable biology (i.e., relatively low Ki-67 [< 55%] <u>slow</u>		
growing, or SSTR-positive based PET imaging);		
2. Prescribed by or in consultation with an oncologist;		
3. Age $\geq 18$ years;		
4. Request is for either Somatuline Depot or unbranded lanreotide;		
4.5.Failure of Sandostatin® LAR Depot, unless contraindicated or clinically adverse		
effects are experienced;		
* Prior authorization may be required for Sandostatin LAR Depot		
5.6.Request meets one of the following (a or b):*		Formatted: Font: Bold
a. Dose does not exceed 120 mg every 4 weeks;		Formatted: Font: Bold
b. Dose is supported by practice guidelines or peer-reviewed literature for the		
relevant off-label use (prescriber must submit supporting evidence).		
*Prescribed regimen must be FDA-approved or recommended by NCCN		
Approval duration: 6 months		
D. Other diagnoses/indications (must meet 1 or 2);	-	Formatted: Indent: Left: 0.25", Keep with next
1. If this drug has recently (within the last 6 months) undergone a label change (e.g.,	~	Formatted: Font: Not Bold
newly approved indication, age expansion, new dosing regimen) that is not yet		Formatted: Font: Not Bold
reflected in this policy, refer to LA.PMN.255		Formatted. Font. Not Bold

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2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

#### **II.** Continued Therapy

A. Acromegaly (must meet all): Formatted: Font: Bold 1. Currently receiving medication via Louisiana Healthcare Connections benefit or Formatted: Font: Bold member has previously met initial approval criteria; Member is responding positively to therapy (see Appendix D); Formatted: List Paragraph 3. If request is for a dose increase, new dose does not exceed 120 mg every 4 weeks. Approval duration: 12 months B. Carcinoid Syndrome and Neuroendocrine Tumors (must meet all): 1. Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Somatuline Depot for a covered indication and has received this medication for at least 30 days; 2. If request is for a dose increase, request meets one of the following (a or b):\* a. New dose does not exceed 120 mg every 4 weeks-; b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence). \*Prescribed regimen must be FDA-approved or recommended by NCCN Approval duration: 12 months C. Other diagnoses/indications (must meet 1 or 2): Formatted: Indent: Left: 0.25", Keep with next 1. If this drug has recently (within the last 6 months) undergone a label change (e.g., Formatted: Font: Bold newly approved indication, age expansion, new dosing regimen) that is not yet Formatted: Font: Bold reflected in this policy, refer to LA.PMN.255 2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53 III. Diagnoses/Indications for which coverage is NOT authorized: **A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – LA.PMN.53 for Medicaid or evidence of coverage documents. **IV. Appendices/General Information** Appendix A: Abbreviation/Acronym Key FDA: Food and Drug Administration **GEP:** gastroenteropancreatic GEP: gastroenteropancreatic NET: neuroendocrine tumor GH: growth hormone GH: growth hormone IGF-I: insulin-like growth factor SSTR: somatostatin receptor

Appendix B: Therapeutic Alternatives

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This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Octreoide acetate (Sandostatin LAR deport) (IM)       Acromegaly: 20-40 mg IM every 4 weeks       See dosing regimen         Carcinoid tumors: 20-30 mg IM every 4 weeks       See dosing regimen       Formatted: Normal. Indent: Luft: 0.25°.         Pormatted: Normal.       Pormatted: Normal.       Formatted: Normal.         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal.       Formatted: Normal.         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal.       Formatted: Normal.         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal.       Formatted: Normal.         Decision and a provide the provide of th	Drug Name	Dosing Regimen	Dose Limit/		Formatted: Normal, Indent: Left: 0.25", Tab stops: Not at 1.22"
(Sandostatin LAR deport) (IM)       20-40 mg IM every 4 weeks       Formatted: Normal         (Deport) (IM)       Carcinoid tumors: 20-30 mg IM every 4 weeks       Formatted: Normal         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal, Indent: Left: 0.25°.         Formatted: Normal, Indent: Left: 0.25°       Formatted: Normal, Indent: Left: 0.25°.         Permeted: Brand name <sup>®</sup> (seneric) when the drug is available by brand name only al generic (Brand name <sup>®</sup> ) when the drug is available by brand and generic.       Formatted: Normal, Indent: Left: 0.25°         prendix C: Contraindication(s): hypersensitivity to lanreotide Boxed warning(s): none reported       Formatted: Indent: Left: 0.25°         prendix D: General Information       Response to acromegaly therapy (e.g., somatostatin analogs, surgical resection, pituitary irradiation) may include:       Formatted: Fort: Bold         • Improved GH or IGF-4] serum concentrations       Improved GH or IGF-4] serum concentrations       Formatted: Fort: Color: Auto         • Gastrointestinal tract tumors include insultinoma, gastrinoma, VIPoma (vasoactive intestinal polypeptide), glucagonoma, and nonfunctioning pancreatic tumors. <td< td=""><td>Ostractida esstata</td><td>Aaromogoly</td><td></td><td></td><td></td></td<>	Ostractida esstata	Aaromogoly			
deport) (IM)       Carcinoid tumors: 20-30 mg IM every 4 weeks       Formatted: Normal. Indent: Left: 0.25°         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal. Indent: Left: 0.25°         Neuroendocrine Tumors: 20-30 mg IM every 4 weeks       Formatted: Normal. Indent: Left: 0.25°         herapeutic alternatives are listed as Brand name@ [generic] when the drug is available by brand name only ad generic (Brand name®) when the drug is available by both brand and generic.       Formatted: Normal. Indent: Left: 0.25°         ppendix C: Contraindications/Boxed Warnings Contraindication(s): hypersensitivity to lanceotide Boxed warning(s): none reported       Formatted: Indent: Left: 0.25°         ppendix D: General Information Response to acromegaly therapy (e.g., somatostatin analogs, surgical resection, pituitary irradiation) may include:       Formatted: Indent: Left: 0.25°         • Improved GH or IGF-14 serum concentrations • Improved tumor mass control NCCN guidelines - Neuroendocrine and Adrenal Tumors • GEP-NETS       Formatted: Font color: Auto         • Parientis with insulinoma, gastrinoma, VIPoma (vasoactive intestinal polypeptide), glucagonoma, and nonfunctioning pancreatic tumors; • For patients with insulinoma, tareotide glancotide should continue treatment with lanceotide if the tumor is functional. Lanceotide may be used in combination with other systemic therapy options.       Formatted: Font color: Auto         Pormatted: Font: Bold       Formatted: Font: Bold         Formatted: Font: Bold       Formatted: Tool: Auto			See dosnig regimen	-M)	Formatted Table
Carcinoid tumors:       20-30 mg IM every 4 weeks         Neuroendocrine Tumors:       20-30 mg IM every 4 weeks         Neuroendocrine Tumors:       20-30 mg IM every 4 weeks         herapeutic alternatives are listed as Brand name <sup>®</sup> (seencic) when the drug is available by brand name only ad generic (Brand name <sup>®</sup> ) when the drug is available by both brand and generic.       Formatted: Normal, Indent: Left: 0.25°.         ppendix C: Contraindications/Boxed Warnings       Formatted: Normal, Indent: Left: 0.25°         Contraindication(s): hypersensitivity to lancotide       Boxed warning(s): none reported         ppendix D: General Information       Response to acromegaly therapy (e.g., somatostatin analogs, surgical resection, pituitary irradiation) may include:       0         0       Improved tumor mass control       NCCN guidelines - Neuroendocrine and Adrenal Tumors         0       GEP-NETS       Gastrointestinal tract tumors include the appendix, stomach, colon and rectum, duodenum, gastric, jejunum and ileum.         •       Por patients with insulinoma, admonfunctioning parcreatic tumors.       Formatted: Font color: Auto         •       Por patients experiencing disease progression on lanceotide should continue treatment with lanceotide if the tumor is functional. Lanceotide may be used in combination with other systemic therapy options.       Formatted: Font: Bold         Pormatted: Font: Bold       Formatted: Font: Bold         Formatted: Font: Bold       Formatted: Table <td><b>( .</b></td> <td>20 40 mg nu every 4 weeks</td> <td></td> <td></td> <td>Formatted: Normal</td>	<b>( .</b>	20 40 mg nu every 4 weeks			Formatted: Normal
20-30 mg IM every 4 weeks       Formatted: Fort: Bold, Underline         Neuroendocrine Tumors:       20-30mg30 mg IM every 4 weeks         herapeutic alternatives are listed as Brand name <sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name <sup>®</sup> ) when the drug is available by both brand and generic.       Formatted: Normal, Indent: Left: 0.25".         ppendix C: Contraindications/Boxed Warnings       Formatted: Normal, Indent: Left: 0.25".       Formatted: Normal, Indent: Left: 0.25".         ppendix C: Contraindications/Boxed Warnings       Formatted: Font: Bold       Formatted: Indent: Left: 0.25".         Contraindication(s): hypersensitivity to lanreotide       Boxed warning(s): none reported       Formatted: Indent: Left: 0.25".         ppendix D: General Information       Response to acromegaly therapy (e.g., somatostatin analogs, surgical resection, pituitary irradiation) may include:       Indent: Left: 0.25".         0       Improved Umor mass control       NCCN guidelines - Neuroendocrine and Adrenal Tumors       General Umors include insulinoma, gastrinoma, VIPoma (vasoactive intestinal polypeptide), glucagonoma, and nonfunctioning pancreatic tumors.       Formatted: Fort color: Auto         0       Patients with insullinoma, lareotide lancetide may be used in combination with oher systemic therapy options.       Formatted: Fort color: Auto         Pormatted: Fort color: Auto       Formatted: Fort: Bold       Formatted: Fort: Bold         Pormatted: Fort: Bold       Formatted: Fort: Bold       Format		Carcinoid tumors:			Formatted: Normal, Indent: Left: 0.25"
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<ul> <li>Formatted: Font: Bold</li> <li><i>ppendix C: Contraindications/Boxed Warnings</i> <ul> <li>Contraindication(s): hypersensitivity to lanreotide</li> <li>Boxed warning(s): none reported</li> </ul> </li> <li><i>ppendix D: General Information</i> <ul> <li>Response to acromegaly therapy (e.g., somatostatin analogs, surgical resection, pituitary irradiation) may include:                 <ul></ul></li></ul></li></ul>					
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HCPCS	Description
Codes	
J1930	Injection, lanreotide, 1 mg
<u>J1932</u>	Injection, lanreotide, (cipla), 1 mg
<u>C9399</u>	Unclassified drugs or biologicals
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Reviews, Revisions, and Approvals	Date	LDH Approval Date
Policy created	01.21	04.28.21
For acromegaly, added confirmatory diagnostic requirements (IGF- I or GH) per PS/ES practice guidelines; per NCCN, specified that thymic/ bronchopulmonary NETs and insulinomas must be SSTR- positive or have hormonal symptoms and added that any grade 3 NETs with favorable biology are also coverable. Template changes applied to other diagnoses/indications and continued therapy section. References reviewed and updated. Added redirection to Sandostatin LAR depot.	06.25.23	<u>10.05.23</u>
Annual review; Added unbranded lanreotide acetate formulation; updated neuroendocrine tumor criteria Grade 3 NET examples and pancreatic tumor examples in Appendix D to align with current NCCN Neuroendocrine Tumors fo the Gastrointestinal Tract, Lung, and Thymus guideline and NCCN compendium; references reviewed and updated.	<u>04.05.24</u>	

#### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

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This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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