Medica (formerly WellFirst Health)

Coverage of any drug intervention discussed in a Medica prior authorization guideline is subject to the limitations and exclusions outlined in the member's benefit certificate or policy and applicable state and/or federal laws.

☒ **Commercial (Small & Large Group)** ☒ **ASO** ☒ **Exchange/ACA**
☒ **Medicare Advantage (MAPD)**

Somatuline (lanreotide) depot MB2202

Covered Service: Yes

Prior Authorization Required: Yes

Additional Information: Prescribed by (or in consultation with) Endocrinologist, Oncologist, gastroenterologist specialists with prior authorization through The Plan Pharmacy Services.

Medicare Policy: Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and the plan secondary coverage. This policy is not applicable to our Medicare Replacement products.

BadgerCare Plus Policy Prescription drug benefits are administered by the Wisconsin Medicaid program. Office administered pharmacy benefits are covered by the plan when covered under the Wisconsin Medicaid fee-for-service program and not paid on a fee-for-service basis by the State of Wisconsin Medicaid program.

Plan Approved Criteria:

1.0 Injections of drugs that are administered at an excessive frequency or dose are not medically necessary. Frequency or dosing are considered excessive when services are performed more frequently or at a higher dose than listed in the FDA-approved package insert, listed in this document or generally accepted by peers and the reason for additional services is not justified by submitted documentation of clinical evidence. Route of administration of injectable drugs should follow the FDA-approved package insert.

2.0 Acromegaly

2.1 Quantity limit: If approved, lanreotide depot will be authorized for quantities of up to one (1) prefilled syringe every four (4) weeks.

2.1.1 Initial: 90 mg every four weeks for three months

2.1.2 Maintenance: Adjust based on GH and/or IGF-1 levels

2.2 Carcinoid syndrome (CS) and neuroendocrine tumors (GEP-NET):

2.2.1 Quantity limit: If approved, lanreotide depot will be authorized for quantities of up to one (1) prefilled syringe every four (4) weeks.

2.2.1.1 GEP-NETs 120 mg every four weeks

2.2.1.2 CS 120 mg every four weeks

Initial Criteria (approval duration 6 months- subject to formulary changes):

1.0 Acromegaly

1.1 Prescribed by, or in consultation with, an endocrinologist; AND

1.2 Diagnosis of acromegaly; AND

1.3 Surgery was ineffective, contraindicated, or not tolerated; AND

1.4 Trial of octreotide LAR was ineffective, contraindicated, or not tolerated

2.0 Neuroendocrine tumors

2.1 Prescribed by, or in consultation with, an oncologist; AND

2.2 Diagnosis of one of the following:

2.3 FDA-approved indication

2.4 Any indication supported by a recommendation from the National Comprehensive Cancer (1, 2A, 2B); AND

2.5 Trial of octreotide LAR was ineffective, contraindicated, or not tolerated

3.0 Carcinoid syndrome

3.1 Prescribed by, or in consultation with, an oncologist, endocrinologist, or gastroenterologist; AND

3.2 Diagnosis of carcinoid syndrome; AND

3.3 Patient is experiencing one of the following:

3.3.1 Flushing

3.3.2 Diarrhea: AND

3.4 Trial of octreotide LAR was ineffective, contraindicated or not tolerated.

Continuation Criteria (approval duration 1 year subject to formulary changes):

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1.0 Acromegaly

1.1 Documentation of a positive clinical response as evidenced by a reduction in cortisol levels

2.0 Neuroendocrine tumors

2.1 Member is being monitored, has not experienced disease progression, and is appropriate to continue therapy with lanreotide depot (Cipla - branded product)/Somatuline.

3.0 Carcinoid syndrome

3.1 Decrease in severity of and occurrence of flushing and diarrhea

3.2 Member is being monitored and is appropriate to continue therapy with lanreotide depot (Cipla - branded product)/Somatuline.

Comment(s):

1.0 Codes and descriptors listed in this document are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member's policy of health coverage with the plan. Inclusion of a code in the table does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

1.1 NDC and HCPCS codes

Medication Name		How Supplied	National Drug Code (NDC)	HCPCS code
Brand	Generic			
Somatuline	Lanreotide	Somatuline Depot 60 mg/0.2 mL prefilled syringe: Somatuline Depot 90 mg/0.3 mL prefilled syringe: Somatuline Depot 120 mg/0.5 mL prefilled syringe:	15054-1060-xx 15054-1090-xx 15054-1120-xx	J1930
	Lanreotide (Cipla –	Lanreotide Acetate 120 mg/0.5 mL prefilled syringe	69097-0870-67	J1932

	branded product)			

Appendix 1: Dose adjustments for acromegaly after the initial three months[1]

GH (ng/mL)	IGF-1	Clinical Symptoms	Lanreotide depot
≤ 1	Normal	Controlled	60 mg every four weeks*†
≥ 1 to ≤ 2.5	Normal	Controlled	Maintain 90 mg every four weeks*†
> 2.5	Elevated	Uncontrolled	120 mg every four weeks*

*Thereafter, dosage should be adjusted according to response of patient as determined by a reduction in serum GH and/or IGF-1 levels; and/or changes in symptoms.
†If patients are controlled on 60 or 90 mg, patients may be considered for an extended dosing interval of 120 mg every six or eight weeks. GH and IGF-1 levels should be obtained six weeks after this change in dosing regimen to evaluate patient response.

2.0 Documentation is expected to be maintained in the member's medical record and to be available to the plan. Every page of the record is expected to be legible and include both the appropriate member identification information (e.g., complete name dates of service(s)), and information identifying the physician or non-physician practitioner responsible for and providing the care of the member. The member's medical record must contain documentation that fully supports the medical necessity for services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

2.1 The medical record must include the following information:

2.1.1 A physician's order

2.1.2 The name of the drug or biological administered

2.1.3 The route of administration

2.1.4 The dosage (e.g., mgs, mcgs, cc's or IU's)

3.0 **NOTE: The use of physician samples or manufacturer discounts does not guarantee later coverage under the provisions of the medical certificate and/or pharmacy benefit. All criteria must be met in order to obtain coverage of the listed drug product.**

	Committee/Source	**Date(s)**
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