Policy Title:	Signifor LAR (pasireotide) injection (intramuscular)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/20/2019		
Revision Date:	12/20/2019		

Purpose: To support safe, effective and appropriate use of Signifor LAR (pasireotide).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Signifor LAR (pasireotide) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Signifor LAR (pasireotide) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Diagnosis of acromegaly;
- Prescribed by an endocrinologist;
- Must fail to achieve full biochemical control (GH, 2.5ug/L and normal IGF1) on high dose treatment with Sandostatin LAR or Somatuline Depot;
- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Continuation of therapy criteria:

  - Documentation is required to show a response to therapy, including;
- Reduction or stabilization in tumor volume from baseline assessed by MRI after initial 6 months of therapy OR
- Mean growth hormone (GH) less than 2.5mcg/L and/or abnormal insulin-like growth factor-1 (IGF-1) level after at least 12 months of initial therapy

Coverage durations (unless listed above):

- Initial coverage criteria = 6 months
- Continuation of therapy = 6 months

Quantity limit

1 injection (maximum 60mg) every 28 days (1 billable unit = 1 mg)

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = *1* mg)**
Cushing 's disease	Initial dose: 10mg every 28 days Maximum dose: 40mg every 28 days	40 units every 28 days
Acromegaly	Initial dose: 40mg every 28 days Maximum dose: 60mg every 28 days	60 units every 28 days

Investigational Use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug Information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2502	Injection, pasireotide long acting, 1mg

References:
Signifor LAR package insert. East Hanover, NJ; Novartis Pharmaceuticals Corporation; January 2019.