Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Signifor (pasireotide)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Signifor (pasireotide).

Signifor (pasireotide) is indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Signifor (pasireotide), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with an endocrinologist
- Must be age 18 years and older
- Must have a diagnosis of Cushing's disease
- Must have a confirmed pituitary source of Cushing's syndrome (chart documentation required)
- Must submit a baseline 24-hour urinary free cortisol level
- Must have previously had pituitary surgery (e.g. transsphenoidal surgery) that was not curative or not be a candidate for surgery
- Must have recent (within 6 months) baseline assessments of the following:
    - Fasting plasma glucose
    - Liver function tests
    - Electrocardiogram
    - Gallbladder ultrasound
    - Pituitary hormones (e.g. TSH/free T4, GH/IGF-1)
- Must provide recent (within 6 months) hemoglobin A1c
    - For members with a hemoglobin A1c value greater than 8%, documentation that anti-diabetic therapy has been optimized must be provided

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon:

- Chart documentation from the provider that the member's disease course has improved based on a reduction in the 24-hour urinary free cortisol level from baseline value, as well as improvements in the signs and symptoms of the disease (e.g. blood pressure, lipid levels, weight).
- Documentation that the following have been assessed within 3 months of initiation of therapy (for initial re-authorization) and at regular intervals thereafter (for annual reauthorizations):
    - Hemoglobin A1c

- Fasting plasma glucose
- Liver function tests
- Gallbladder ultrasound
- Pituitary hormones (e.g. TSH/free T4, GH/IGF-1)
- Electrocardiogram

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 3 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Signifor	60 ampules per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Signifor [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation
2. Colao A, Petersenn S, Newell-Price J, et al. A 12-month phase 3 study of pasireotide in Cushing's Disease. *N Engl J Med* 2012;366:914-24
3. Boscaro M, Ludlam WH, Atkinson B, et al. Treatment of pituitary-dependent Cushing's Disease with the multireceptor ligand somatostatin analog pasireotide (SOM230): a multicenter, phase II trial. *Endocrinol Metab* 2009;94:115-122
4. Duran-Perez EG, Moreno-Loza OT, Carrasco-Tobon G, et al. Optimal management of Cushing Syndrome. *Research and Reports in Endocrine Disorders* 2012;2:19-30
5. Fleseriu M, Petersenn S. Medical management of Cushing's disease: what is the future? *Pituitary* 2012;15:330-341
6. Pedroncelli AM. Medical treatment of Cushing's Disease: Somatostatin analogues and pasireotide. *Neuroendocrinology* 2010;92 (suppl 1):120-124
7. Feelders RA, de Bruin C, Pereira AM, et al. Pasireotide alone or in combination with cabergoline and ketoconazole in Cushing's disease. *N Engl J Med* 2010;362(19):1846-1848
8. Pivonello R, De Martino MC, Cappabianca P, et al. The medical treatment of Cushing's disease: effectiveness of chronic treatment with the dopamaine agonist cabergoline in patient unsuccessfully treated by surgery. *J Clin Metab* 2009;94:223-230.
9. Vilar L, Naves LA, Azevedo MF, et al. Effectiveness of cabergoline in monotherapy and combined with ketoconazole in the management of Cushing's disease. *Pituitary* 2010;13:123-129

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*