RX.PA.031.MPC Signifor® (Pasireotide)

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.

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

PROCEDURE

A. 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 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

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. Signifor will be considered investigational or experimental for any other use and will not be covered.

D. 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:

MPC Renewal:

- 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

Non-MPC Renewal:

- Members who have previously been taking Signifor and are requesting a non-MPC renewal should be considered under criterion A (Initial Authorization Criteria)
- Member has not been receiving medication samples for Signifor; AND
- Provider has documented clinical response of member's condition which has stabilized or improved based upon the prescriber's assessment

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, if required for the plan and level of request.

HCPCS Code(s):

Code	Description
J2502	Injection, pasireotide long acting, 1 mg

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

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Selected Revision *Addition of MPC vs Non-MPC Renewal Criteria*	*08/2022*
Annual review	*02/2022*
Addition of dosing requirements and off-label restrictions	*12/2021*
P&T Review	*11/2020*