

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

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, 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

Signifor (Pasireotide)

POLICY NUMBER: RX.PA.031.MPC

REVISION DATE: 02/2020

PAGE NUMBER: 3 of 3

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 dopamine 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