

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2024 P 1093-12
Program	Prior Authorization/Notification
Medication	Signifor [®] (pasireotide diaspartate)
P&T Approval Date	2/2013, 5/2013, 11/2013, 11/2014, 11/2015, 9/2016, 9/2017, 9/2018,
	9/2019, 9/2020, 9/2021, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

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

2. Coverage Criteria^a:

A. Initial Authorization

- 1. Signifor will be approved based on <u>both</u> of the following criteria:
 - a. Diagnosis of endogenous Cushing's disease (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids)

-AND-

b. <u>One</u> of the following:

- (1) Pituitary surgery has not been curative for the patient
- (2) Patient is not a candidate for pituitary surgery

Authorization will be issued for 12 months.

B. <u>Reauthorization</u>

- 1. Signifor will be approved based on the following criterion:
 - a. Documentation of positive clinical response to Signifor therapy

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.



3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and reauthorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Signifor [package insert]. Bridgewater, NJ: Recordati Rare Diseases, Inc.; July 2024.

Program	Prior Authorization/Notification - Signifor (pasireotide diaspartate) Notification
Change Control	
2/2013	New program.
5/2013	Initial authorization period revised based upon consultant feedback.
11/2013	Formatting update. Removal of dose information in Background Section.
11/2014	Annual review with no change to coverage.
11/2015	Annual review. Updated background info. Changed authorization period from 3 months to 6 months. Updated references.
9/2016	Annual review. No change to coverage criteria.
9/2017	Annual review with no changes to coverage criteria.
9/2018	Annual review with no changes to coverage criteria. Updated reference.
9/2019	Annual review with no changes to coverage criteria. Updated reference.
9/2020	Annual review with no changes to coverage criteria. Updated reference.
9/2021	Annual review with no changes to coverage criteria. Updated reference.
10/2022	Annual review with no changes to coverage criteria. Added state mandate footnote.
10/2023	Annual review with no changes to coverage criteria.
10/2024	Annual review. Updated initial authorization duration to 12 months and updated reference.