Dear Healthcare Provider,

Recordati Access, Resources, and Engagement (R.A.R.E.), a patient and provider support program within Recordati Rare Diseases Inc. has developed an:

**Signifor® LAR (pasireotide) for injectable suspension for Cushing’s Disease Letter of Medical Necessity and Intent to Treat TEMPLATE**

The purpose of this template letter is to assist your office in developing a customized Letter of Medical Necessity which outlines the medical justification for Signifor® LAR therapy. Often, by submitting a Letter of Medical Necessity tailored around the history and current treatment needs of your patient, insurance plans may better understand the reasoning for Signifor® LAR.

Please note - this letter template should only be used as a guide. Each patient will have their own unique and specific reasons for needing Signifor® LAR therapy. In addition, each insurance plan may have their own rules and guidelines for approving Signifor® LAR.

This sample letter and related information are provided for informational purposes only. It is the responsibility of the HCP and/or their office staff, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient. Recordati Rare Diseases (RRD) does not guarantee coverage or reimbursement for the product. There is no requirement that any patient or healthcare provider use any RRD product in exchange for this information, and this template is not meant to substitute for a prescriber’s independent medical decision-making.

For full Prescribing Information, please go to www.SIGNIFORLAR.com.

Sincerely,

Recordati Access, Resources, and Engagement (R.A.R.E.) Team

Phone: (888) 855-RARE (7273)

Fax: (855) 813-2039

Icon

Description automatically generated

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PP-SIGL-US-0117

**[ON OFFICE LETTERHEAD INCLUDING PROVIDER NAME AND ADDRESS]**

Signifor® LAR (pasireotide) for injectable suspension

**Letter of Medical Necessity and Intent to Treat**

**TEMPLATE**

**[Date]**

**[Insurance Name]**

**[Insurance Address]**

Patient Name: **[Patient Name]**

Patient Date of Birth: **[Patient DOB]**

Policy Number: **[Policy Number]**

Group Number: **[Group Number]**

Subject: Intent to Treat with Signifor® LAR (pasireotide) for injectable suspension

To Whom It May Concern:

I am writing on behalf of my patient **[Patient Name]**, who has been diagnosed with Cushing’s disease. I am writing to support the treatment of **[Patient Name]** with Signifor® LAR. Signifor® LAR is a somatostatin analog indicated for the treatment of patients with Cushing’s disease for whom pituitary surgery is not an option or has not been curative.1

Cushing’s disease:

Cushing’s disease is a rare endocrine disorder caused by excessive cortisol, a hormone that regulates metabolism, reduces inflammation, and helps the body respond to stress.2

Summary of Patient’s Diagnosis:

* **[Description of lab tests, imaging, etc. that supports diagnosis of Cushing’s disease]**

Summary of Patient’s History:

* **[Description of symptoms]**
* **[Description of surgical procedures related to Cushing’s disease]**
* **[List of previous prescription medications related to Cushing’s disease and response]**
* **[If not previously mentioned, rationale for not using prescription medications that are requested by insurance plan]**
* **[List of tests needed before starting Signifor® LAR (fasting plasma glucose (FPG) and hemoglobin A1c (HbA1c), assessment of liver function, baseline electrocardiogram, serum potassium and serum magnesium levels)]**

Rationale for Treatment:

It is my medical opinion that initiating Signifor® LAR for **[patient’s name]** is appropriate and medically necessary at this time. My intended use of Signifor® LAR will be to treat at **[insert dose]** mg administered by intramuscular injection once every 4 weeks (every 28 days)1. I will monitor cortisol levels as well as response to therapy. If needed, I may titrate the dose of Signifor® LAR as outlined in Section 2.4 of the approved Prescribing Information.

In the Signifor® LAR Phase 3 study, the proportion of patients with Cushing’s Disease with a mean urinary free cortisol (mUFC) response at month 7 was 39.2% (29/74) in the 10 mg arm and 40.8% (31/76) in the 30mg arm.1 After 4 months of treatment, trial protocol allowed for a dosage increase for patients with a mUFC > 1.5 x ULN.1 In the 10mg arm, 41.9% (31/74) of patients were up-titrated to 30mg, and in the 30mg arm, 36.8% (28/76) of patients were up-titrated to 40mg. A mUFC response was defined as mUFC ≤ Upper Limit of Normal (ULN; ULN = 166.5 nmol/24 hours).1 Normalization of cortisol concentrations (or action at its receptors) is the primary objective in the treatment of patients with Cushing’s disease.3

I would appreciate your evaluation of this request and ask that you approve Signifor® LAR. If you have any questions or wish to conduct a Peer to Peer discussion, feel free to contact me at **[phone number]**.

Sincerely,

**[HCP Name and participating provider number]**

Enclosures: **[List of documentation described in above letter]**

References:

1. Signifor® LAR (pasireotide) for injectable suspension [prescribing information]. Bridgewater, NJ: Recordati Rare Diseases Inc.; 2020.
2. Miller, BS et al. Evaluation and treatment of patients with hypercortisolism: A Review. *JAMA Surg*. 2020; 155:1152-1159.
3. Nieman, L et al. Treatment of Cushing’s Syndrome: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2015; 100(8):2807-2831.