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 Acromegaly 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)

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**[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 acromegaly. 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 acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.1

Acromegaly:

Acromegaly is a rare endocrine disorder usually caused by a tumor in the pituitary gland that secretes growth hormone (GH), resulting in increased levels of both GH and insulin-like growth factor-1 (IGF-1) in the body.2 Prolonged exposure to these hormones results in somatic overgrowth, physical disfigurement, systemic comorbidities, and increased risk of morality.2,3

Summary of Patient’s Diagnosis:

* **[Description of lab tests, imaging, etc. that supports diagnosis of acromegaly]**

Summary of Patient’s History:

* **[Description of symptoms]**
* **[Description of surgical procedures related to acromegaly]**
* **[List of previous prescription medications related to acromegaly 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 growth hormone (GH) and insulin-like growth factor-1 (IGF-1) 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 a Signifor LAR® clinical trial in drug naïve patients with acromegaly, patients received either Signifor® LAR 40mg or octreotide LAR 20mg for 12 months. After 3 and 6 months of treatment, patients could be up-titrated to either Signifor® LAR 60mg or octreotide LAR 30mg, depending on GH and IGF-1 levels.1 At 12 months, the proportion of patients with mean GH levels less than 2.5 mcg/L and a normal IGF-1 level was 31.3% (55/176) for Signifor® LAR (40-60mg) vs 19.2% (35/182) for octreotide LAR (20-30mg).1,4 Normalization of GH and IGF-1 concentrations is the primary objective in the treatment of patients with acromegaly.3

In addition, Signifor LAR® was studied in patients with acromegaly who were inadequately controlled on first-generation somatostatin analogs (either octreotide LAR 30 mg or lanreotide autogel 120 mg). At 24 weeks, the proportion of patients with a mean GH level less than 2.5 mcg/L and normal IGF-1 levels were 15.4% (10/65) for Signifor® LAR 40mg and 20.0% (13/65) for Signifor® LAR 60mg compared to 0% (0/68) who continued on octreotide LAR or lanreotide autogel therapy.1,5

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. Colao A et al. Acromegaly. *Nat Rev Dis Primers*. 2019; 5(1):20.
3. Katznelson L et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2014; 99(11):3933-3951.
4. Colao, A et al. Pasireotide Versus Octreotide in Acromegaly: A Head-to-Head Superiority Study. *J Clin Endocrinol Metab.* 2014; 99(3):791-799.
5. Gadelha, M et al. Pasireotide versus continued treatment with octreotide or lanreotide in patients with inadequately controlled acromegaly (PAOLA): a randomized, phase 3 trial. *Lancet Diabetes Endocrinol.* 2014; 2(11): 875-84.