SPECIALTY GUIDELINE MANAGEMENT

SIGNIFOR LAR (pasireotide injectable suspension)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option

B. Treatment of patients with Cushing’s disease for whom pituitary surgery is not an option or has not been curative

All other indications are considered experimental/investigational and are not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. For acromegaly:
   1. For initial approval: Laboratory report indicating high pretreatment insulin-like growth factor-1 (IGF-1) level and chart notes indicating an inadequate or partial response to surgery or a clinical reason for not having surgery.
   2. For continuation: Laboratory report indicating normal current IGF-1 levels or chart notes indicating that the member’s IGF-1 level has decreased or normalized since initiation of therapy

B. Cushing’s syndrome: Chart notes indicating that surgery is not an option for the member or was not curative.

III. CRITERIA FOR INITIAL APPROVAL

A. Acromegaly

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

1. Member has a high pretreatment IGF-1 level for age and/or gender based on the laboratory reference range.
2. Member had an inadequate or partial response to surgery OR there is a clinical reason why the member has not had surgery.

B. Cushing’s syndrome/disease

Authorization of 12 months may be granted for the treatment of Cushing’s disease/syndrome when the member has had surgery that was not curative OR the member is not a candidate for surgery.
IV. CONTINUATION OF THERAPY

A. Acromegaly
Authorization of 12 months may be granted for continuation of therapy for acromegaly when the member’s IGF-1 level has decreased or normalized since initiation of therapy.

B. Cushing’s syndrome/disease
Authorization of 12 months may be granted for continuation of therapy for Cushing’s syndrome/disease when the member meets ALL initial authorization criteria.

V. REFERENCES