SPECIALTY GUIDELINE MANAGEMENT

SIGNIFOR LAR (pasireotide injectable suspension)

POLICY
A. 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 Indication
Signifor LAR is 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.

All other indications are considered experimental/investigational and are not a covered benefit.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
• Insulin-like growth factor 1 (IGF-1) level

C. INITIAL CRITERIA FOR APPROVAL
1. Acromegaly
   Authorization of 12 months may be granted to members who are prescribed Signifor LAR for the treatment of acromegaly when ALL of the following criteria are met:
   a. Member has clinical evidence of acromegaly (see Appendix A)
   b. Member has a high pretreatment IGF-1 level for age and/or gender (see Appendix B)
   c. Member had an inadequate or partial response to surgery OR there is a clinical reason why the member has not had surgery (See Appendix C)

D. CONTINUATION OF THERAPY
1. Acromegaly
   Authorization of 12 months may be granted to members who are prescribed Signifor LAR for continuation of therapy for acromegaly when ALL of the following criteria are met:
   a. Member has clinical evidence of acromegaly (see Appendix A)
   b. Member’s IGF-1 level has decreased or normalized since initiation of therapy

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

1. Dosing Limits
   • 60 mg per 28 days

F. APPENDICES

Appendix A: Clinical Evidence of Acromegaly (not all-inclusive)
• Frontal bossing
• Coarse facial features
• Thick lips
• Protruding jaw with widely spaced teeth
• Large hands and feet
Appendix B: Normal IGF-1 Levels for Age and Gender

The normal range varies based on the laboratory performing the analysis. One must obtain lab-specific values to make this determination.

Appendix C: Clinical Reasons for Not Having Surgery

- The member has medically unstable conditions (poor surgical candidate)
- The member is at high risk for complications of anesthesia because of airway difficulties
- The member has major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension and uncontrolled diabetes
- The member refuses surgery or prefers the medical option over surgery
- There is a lack of an available skilled surgeon

REFERENCES