Reference number(s)
2206-A

STANDARD MEDICARE PART B MANAGEMENT

KRYSTEXXA (pegloticase)

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 Indication
Krystexxa is indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Limitations of Use
Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions for continuation of therapy: Documentation (e.g., chart notes, lab test results) of a response to therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms)

III. CRITERIA FOR INITIAL APPROVAL

Chronic gout
Authorization of 12 months may be granted for treatment of chronic gout when BOTH of the following criteria are met:
A. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies.
B. The member is refractory to conventional therapy (e.g., allopurinol, febuxostat) at maximum medically appropriate dose.or the member has a clinical reason to avoid therapy with all conventional therapies.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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

A. The member is currently receiving therapy with Krystexxa.
B. Krystexxa is being used to treat an indication enumerated in Section II.
C. The member has NOT had two consecutive serum uric acid levels above 6 mg/dL since starting treatment with Krystexxa.
D. The member is receiving benefit from therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares).

V. REFERENCES

1. Krystexxa [package insert]. Deerfield, IL: Horizon Therapeutics USA, Inc.; March 2021.