Reference number
1803-A

SPECIALTY GUIDELINE 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 are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Chronic gout
Authorization of 12 months may be granted for members with a diagnosis of chronic gout when ALL of the following criteria are met:
A. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies.
B. The member has at least 2 flares per year that were inadequately controlled by colchicine or NSAIDs or at least 1 gout tophus or gouty arthritis.
C. Member has had an inadequate response to or a clinical reason for not completing at least a three-month trial (see Appendix) with the following medications at the medically appropriate maximum doses:
    1. Allopurinol or febuxostat
    2. Probenecid (alone or in combination with allopurinol or febuxostat)

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in all members (including new members) requesting reauthorization for chronic gout who meet ALL initial authorization criteria and have NOT had two consecutive uric acid levels above 6 mg/dL since starting treatment with Krystexxa.

IV. APPENDIX

Clinical reasons for not completing a three-month trial with allopurinol, febuxostat, and probenecid (examples):
A. Member experienced a severe allergic reaction to the medication
B. Member experienced toxicity with the medication
C. Member could not tolerate the medication

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D. Member's current medication regimen has a significant drug interaction
E. Member has severe renal dysfunction (allopurinol)
F. Member has known blood dyscrasias or uric acid kidney stones (probenecid)
G. Member has renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less) (probenecid)
H. Member has end stage renal impairment (febuxostat)

V. REFERENCES

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