Krystexxa (pegloticase)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

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

FDA-Approved Indications

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

POLICY

Documentation Required

Chart notes regarding trial and failure of prior therapies, documentation of lifestyle modifications, and serum uric acid levels prior to and after intitating treatment with the requested drug

Criteria for Initial Approval

A. Chronic gout

Authorization of 6 months may be granted for members with a diagnosis of chronic gout that is refractory to conventional treatment when ALL of the following criteria are met:

1. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies
2. Krystexxa is being prescribed by or in consultation with a rheumatologist
3. Member has a clinical reason for not completing at least a three-month trial (see Appendix) with BOTH of the following at the maximum tolerated doses:
   a.) Allopurinol or febuxostat
   b.) Probenecid (alone or in combination with allopurinol or febuxostat)

OR

4. Member has had an inadequate response to BOTH of the above at the maximum tolerated doses, with an inadequate response defined as serum uric acid levels greater than or equal to 6 mg/dL AND persistent, recurrent gout attacks in one or more affected joints
5. Member has implemented and maintained appropriate lifestyle modifications, including weight loss if obese, avoiding or limiting alcohol intake, and avoiding or limiting dietary intake of meats and fish with high purine content
6. Member has a baseline serum uric acid level greater than 6 mg/dL prior to initiation of treatment with the requested drug
7. Member is symptomatic as evidenced by pain in one or more affected joints that has been evaluated for and is not attributed to another cause
8. Concomitant use of medications (e.g. diuretics, cyclosporine, aspirin) known to precipitate gout attacks have been evaluated and changed if possible

Continuation of Therapy

Authorization of 12 months may be granted for all members (including new members) with a diagnosis of chronic gout that have NOT had two consecutive uric acid levels above 6 mg/dL since starting treatment with Krystexxa, have maintained appropriate lifestyle modifications, and have experienced an improvement in symptoms, as evidenced by a reduction in gout-related pain in one or more affected joints.

Dosage and Administration

Coverage is limited to 8 mg every two weeks

Appendix

Clinical reasons for not completing a three-month trial with allopurinol, febuxostat, and probenecid (examples):

1. Member experienced a severe allergic reaction to the medication
2. Member experienced toxicity with the medication
3. Member could not tolerate the medication
4. Member's current medication regimen has a significant drug interaction
5. Member has severe renal dysfunction (allopurinol)
6. Member has known blood dyscrasias or uric acid kidney stones (probenecid)
7. Member has renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less) (probenecid)
8. Member has end stage renal impairment (febuxostat)

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

J2507- Injection, pegloticase, 1 mg

REFERENCES

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- Sivera F, Andres M, Carmona L, et al. Multinational evidence-based recommendations for the diagnosis and management of gout: integrating systemic literature review and expert opinion of a broad panel of rheumatologists in the 3e initiative. *Ann Rheum Dis.* 2014;73(2):328-335.
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POLICY HISTORY

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