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.

The recommended dosage is Krystexxa 8 mg every two weeks given as an intravenous infusion, co-administered with weekly methotrexate 15 mg orally. Krystexxa alone may be used in patients for whom methotrexate is contraindicated or not clinically appropriate.

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

POLICY

Documentation Required
Chart notes regarding trial and failure of or contraindication or documented intolerance to prior therapies, documentation of lifestyle modifications, serum uric acid and glucose-6-phosphate dehydrogenase (G6PD) levels, number of gout attacks, and documentation of course of subcutaneous tophi prior to and after initiating treatment with the requested drug.

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For continuation of therapy requests: 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 and/or flares).

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. Patient is 18 years of age or older.
2. Patient does NOT have a glucose-6-phosphate dehydrogenase (G6PD) deficiency
3. Patient has a confirmed diagnosis of chronic gout and all of the following are met:
    a.) Serum uric acid level greater than 6 mg/dL; AND
        i. ≥ 2 persistent, recurrent gout attacks in one or more affected joints in the previous 12 months; OR
        ii. ≥ 1 nonresolving subcutaneous tophi
4. Patient meets one of the following:
    a.) Has previously received ≥ 3 months of concomitant therapy with colchicine, NSAIDs, or glucocorticoids used for prophylaxis of acute gout attacks prior to initiating therapy with Krystexxa
    b.) Will receive concomitant therapy with colchicine, NSAIDs, or glucocorticoids used for prophylaxis of acute gout attacks during, at minimum, the first three months of receiving therapy with Krystexxa
    c.) Has a contraindication or documented intolerance to colchicine, NSAIDs, AND glucocorticoids used for prophylaxis of acute gout attacks
5. Patient meets one of the following:
    a.) 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:
        i. Allopurinol or febuxostat
        ii. Probenecid (alone or in combination with allopurinol or febuxostat)
    b.) Had an inadequate response to BOTH of the above at the maximum tolerated doses, with an inadequate response defined as ALL of the following:
        i. Serum uric acid levels greater than or equal to 6 mg/dL; AND
            1. ≥ 2 persistent, recurrent gout attacks in one or more affected joints in the previous 12 months; OR
            2. ≥ 1 nonresolving subcutaneous tophi
6. Patient has implemented and maintained appropriate lifestyle modifications, including weight loss if obese, avoiding or limiting alcohol and high-fructose corn syrup intake, and avoiding or limiting dietary intake of meats and fish with high purine content
7. Patient 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) known to precipitate gout attacks have been evaluated and changed if possible
9. Krystexxa will be co-administered with methotrexate unless contraindicated or not clinically appropriate
10. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies
11. Krystexxa is being prescribed by or in consultation with a rheumatologist

Continuation of Therapy

A. Authorization of **12 months** may be granted for all members (including new members) with a diagnosis of chronic gout that is refractory to conventional treatment when ALL of the following criteria are met:

1. Patient is 18 years of age or older.

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2. Patient does not have a glucose-6-phosphate dehydrogenase (G6PD) deficiency
3. Patient meets one of the following:
    a.) Has previously received ≥ 3 months of concomitant therapy with colchicine, NSAIDs, or glucocorticoids used for prophylaxis of acute gout attacks prior to initiating therapy with Krystexxa
    b.) Will receive concomitant therapy with colchicine, NSAIDs, or glucocorticoids used for prophylaxis of acute gout attacks during, at minimum, the first three months of receiving therapy with Krystexxa
    c.) Has a contraindication or documented intolerance to colchicine, NSAIDs, AND glucocorticoids used for prophylaxis of acute gout attacks
4. Patient meets one of the following:
    a.) 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:
        i. Allopurinol or febuxostat
        ii. Probenecid (alone or in combination with allopurinol or febuxostat)
    b.) Had an inadequate response to BOTH of the above at the maximum tolerated doses, with an inadequate response defined as ALL of the following:
        i. Serum uric acid levels greater than or equal to 6 mg/dL; AND
            1. ≥ 2 persistent, recurrent gout attacks in one or more affected joints in the previous 12 months; OR
            2. ≥ 1 nonresolving subcutaneous tophi
5. Patient has NOT had two consecutive uric acid levels above 6 mg/dL since starting treatment with Krystexxa
6. Patient has maintained appropriate lifestyle modifications since starting treatment with Krystexxa
7. Patient is experiencing benefit from therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares).
8. Krystexxa will be co-administered with methotrexate unless contraindicate or not clinically appropriate
9. Krystexxa will NOT be used concomitantly with oral urate-lowering therapies
10. Krystexxa is being prescribed by or in consultation with a rheumatologist

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, not all inclusive):

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)
9. Member has a history of CVD or a new CV event (febuxostat)

PROCEDURES AND BILLING CODES

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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

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POLICY HISTORY

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