JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP108
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	Subject **Krystexxa**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Krystexxa

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I. POLICY

A. Krystexxa (pegloticase) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. Krystexxa may be approved for patients who meet the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing all the following:
      a. Diagnosis of chronic gout
      b. Patient 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. Patient has had one of the following:
         I. an inadequate response to at least a three-month trial with the or a clinical reason for not completing at least a three-month trial with the following medications at the medically appropriate maximum doses:
            i. Allopurinol or febuxostat
            ii. Probenecid (alone or in combination with allopurinol or febuxostat)
         II. a clinical reason for not completing trials with allopurinol or febuxostat, and probenecid, such as one of the following:
            i. Patient has experienced a severe allergic reaction to the medication
            ii. Patient has experienced toxicity with the medication
            iii. Patient could not tolerate the medication
            iv. Patient's current medication regimen has a significant drug interaction
            v. Patient has known blood dyscrasias or uric acid kidney stones (probenecid)
            vi. Patient has severe renal dysfunction (allopurinol)
            vii. Patient has renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less) (probenecid)
            viii. Patientr has end stage renal impairment (febuxostat)
            ix. Patient has a history of CVD or a new CV event (febuxostat)
      d. Patient meets one of the following scenarios:

I. Krystexxa will be co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation
II. Patient has one of the following contraindications or clinical reasons to avoid oral methotrexate therapy:
i. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
ii. Breastfeeding
iii. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
iv. Elevated liver transaminases
v. History of intolerance or adverse event
vi. Hypersensitivity
vii. Interstitial pneumonitis or clinically significant pulmonary fibrosis
viii. Myelodysplasia
ix. Pregnant or currently planning pregnancy
x. Renal impairment
xi. Significant drug interaction

e. Krystexxa will not be used concomitantly with oral urate-lowering therapies

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient meets the following:
1. Patient is 18 years of age or older.
2. Patient meets one of the following scenarios:
a. Krystexxa will be co-administered with weekly oral methotrexate and folic acid or folinic acid supplementation
b. Patient has one of the following contraindications or clinical reasons to avoid oral methotrexate therapy:
I. Clinical diagnosis of alcohol use disorder, alcoholic liver disease, or other chronic liver disease
II. Breastfeeding
III. Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
IV. Elevated liver transaminases
V. History of intolerance or adverse event
VI. Hypersensitivity
VII. Interstitial pneumonitis or clinically significant pulmonary fibrosis
VIII. Myelodysplasia
IX. Pregnant or currently planning pregnancy
X. Renal impairment
XI. Significant drug interaction
3. Patient has not had two consecutive uric acid levels above 6 mg/dL since starting treatment with Krystexxa
4. Patient is experiencing benefit from therapy, evidenced by at least one of the following:
a. serum uric acid levels< 6 mg/dL
b. reduction of tophi
c. reduction of symptoms and/or flares
5. Krystexxa will not be used concomitantly with oral urate-lowering therapies

IV. EXCLUSIONS

A. Krystexxa will not be covered for the following:

1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, pegloticase, 1 mg	J2507

VII. REFERENCES

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10. Febuxostat [prescribing information]. Berkeley Heights, NJ: Hikma Pharmaceuticals USA Inc.; May 2023.

VIII. APPROVALS

Signature on file at JHHP

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