

Krystexxa® (pegloticase) (Intravenous)

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I. Length of Authorization

Coverage is provided for six months and will be eligible for renewal.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Krystexxa 8 mg/mL single-use vial: 2 vials every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 16 billable units every 28 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Patients at higher risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency have been screened and found negative for G6PD before starting Krystexxa; **AND**
- Documentation of baseline serum uric acid level ≥ 7 mg/dL (current lab reports are required for renewal); **AND**

Universal Criteria ^{1,2}

- Therapy will not be given in combination with other urate lowering therapies such as allopurinol, febuxostat, probenecid, lesinurad, etc.; **AND**

Chronic Gout † Φ ¹

- Documented contraindication, intolerance, or clinical failure (i.e., inability to reduce serum uric acid to < 6 mg/dL) during a minimum (3) month trial on previous therapy with maximum tolerated dose of xanthine oxidase inhibitors (e.g., allopurinol or febuxostat) or uricosuric agents (e.g., probenecid, lenisurad, etc.); **AND**
- Patient has one of the following:

- 2 or more gout flares per year that were inadequately controlled by colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), or oral or injectable corticosteroids; **OR**
- At least one (1) nonresolving subcutaneous tophi; **OR**
- Evidence of radiographic damage of any modality that is attributable to gout; **AND**
 - Used in combination with methotrexate; **OR**
 - Used as a single agent if methotrexate is contraindicated or clinically not appropriate

† FDA-labeled indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment (i.e., reduction of symptoms, reduction of tophi); **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis, infusion reactions, exacerbation of congestive heart failure, hemolytic reactions (including methemoglobinemia and hemolysis), etc.; **AND**
- Documentation of serum uric acid level ≤ 6 mg/dL prior to scheduled infusion

V. Dosage/Administration ¹

Indication	Dose
Chronic Gout	8 mg given as an intravenous infusion every two weeks. <ul style="list-style-type: none"> • Patient should receive gout flare prophylaxis with a NSAID or colchicine starting at least 1 week prior to therapy and continuing for at least 6 months • When coadministered with methotrexate, start weekly oral methotrexate 15 mg and folic or folinic acid supplementation at least 4 weeks prior.
<i>Note: There is no controlled trial data available on the safety and efficacy of re-treatment with Krystexxa after stopping treatment for longer than 4 weeks. Due to the immuno-genicity of Krystexxa, patients receiving re-treatment may be at increased risk of anaphylaxis and infusion reactions. Therefore, patients receiving re-treatment after a drug-free interval should be monitored carefully.</i>	

VI. Billing Code/Availability Information

HCPCS Code:

- J2507 – Injection, pegloticase, 1 mg: 1 billable unit = 1mg

NDC:

- Krystexxa 8 mg/mL single-use vial: 75987-0080-xx

VII. References

1. Krystexxa [package Insert]. Lake Forest, IL; Horizon Pharma Rheumatology, LLC; July 2022. Accessed July 2022.
2. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for the Management of Gout. *Arthritis Care Res (Hoboken)*. 2020 Jun; 72(6):744-760. Epub 2020 May 11.
3. Richette P, Doherty M, Pascual E, et al. 2016 updated EULAR evidence-based recommendations for the management of gout. *Annals of the Rheumatic Diseases* 2017;76:29-42.
4. Qaseem A, Harris RP, Forciea MA, et al. Management of Acute and Recurrent Gout: A Clinical Practice Guideline From the American College of Physicians. *Ann Intern Med*. 2017;166(1):58-68.
5. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. *JAMA*. 2011;306(7):711-720. doi:10.1001/jama.2011.1169.
6. Botson J, Tesser J, Bennett R, et al. Pegloticase in Combination With Methotrexate in Patients With Uncontrolled Gout: A Multicenter, Open-label Study (MIRROR). *J Rheumatol*. 2021 May;48(5):767-774. doi: 10.3899/jrheum.200460. Epub 2020 Sep 15.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M1A.00X0	Idiopathic chronic gout, unspecified site, without tophus (tophi)
M1A.00X1	Idiopathic chronic gout, unspecified site, with tophus (tophi)
M1A.0110	Idiopathic chronic gout, right shoulder, without tophus (tophi)
M1A.0111	Idiopathic chronic gout, right shoulder, with tophus (tophi)
M1A.0120	Idiopathic chronic gout, left shoulder, without tophus (tophi)
M1A.0121	Idiopathic chronic gout, left shoulder, with tophus (tophi)
M1A.0190	Idiopathic chronic gout, unspecified shoulder, without tophus (tophi)
M1A.0191	Idiopathic chronic gout, unspecified shoulder, with tophus (tophi)
M1A.0210	Idiopathic chronic gout, right elbow, without tophus (tophi)
M1A.0211	Idiopathic chronic gout, right elbow, with tophus (tophi)
M1A.0220	Idiopathic chronic gout, left elbow, without tophus (tophi)
M1A.0221	Idiopathic chronic gout, left elbow, with tophus (tophi)
M1A.0290	Idiopathic chronic gout, unspecified elbow, without tophus (tophi)
M1A.0291	Idiopathic chronic gout, unspecified elbow, with tophus (tophi)
M1A.0310	Idiopathic chronic gout, right wrist, without tophus (tophi)
M1A.0311	Idiopathic chronic gout, right wrist, with tophus (tophi)
M1A.0320	Idiopathic chronic gout, left wrist, without tophus (tophi)

ICD-10	ICD-10 Description
M1A.0321	Idiopathic chronic gout, left wrist, with tophus (tophi)
M1A.0390	Idiopathic chronic gout, unspecified wrist, without tophus (tophi)
M1A.0391	Idiopathic chronic gout, unspecified wrist, with tophus (tophi)
M1A.0410	Idiopathic chronic gout, right hand, without tophus (tophi)
M1A.0411	Idiopathic chronic gout, right hand, with tophus (tophi)
M1A.0420	Idiopathic chronic gout, left hand, without tophus (tophi)
M1A.0421	Idiopathic chronic gout, left hand, with tophus (tophi)
M1A.0490	Idiopathic chronic gout, unspecified hand, without tophus (tophi)
M1A.0491	Idiopathic chronic gout, unspecified hand, with tophus (tophi)
M1A.0510	Idiopathic chronic gout, right hip, without tophus (tophi)
M1A.0511	Idiopathic chronic gout, right hip, with tophus (tophi)
M1A.0520	Idiopathic chronic gout, left hip, without tophus (tophi)
M1A.0521	Idiopathic chronic gout, left hip, with tophus (tophi)
M1A.0590	Idiopathic chronic gout, unspecified hip, without tophus (tophi)
M1A.0591	Idiopathic chronic gout, unspecified hip, with tophus (tophi)
M1A.0610	Idiopathic chronic gout, right knee, without tophus (tophi)
M1A.0611	Idiopathic chronic gout, right knee, with tophus (tophi)
M1A.0620	Idiopathic chronic gout, left knee, without tophus (tophi)
M1A.0621	Idiopathic chronic gout, left knee, with tophus (tophi)
M1A.0690	Idiopathic chronic gout, unspecified knee, without tophus (tophi)
M1A.0691	Idiopathic chronic gout, unspecified knee, with tophus (tophi)
M1A.0710	Idiopathic chronic gout, right ankle and foot, without tophus (tophi)
M1A.0711	Idiopathic chronic gout, right ankle and foot, with tophus (tophi)
M1A.0720	Idiopathic chronic gout, left ankle and foot, without tophus (tophi)
M1A.0721	Idiopathic chronic gout, left ankle and foot, with tophus (tophi)
M1A.0790	Idiopathic chronic gout, unspecified ankle and foot, without tophus (tophi)
M1A.0791	Idiopathic chronic gout, unspecified ankle and foot, with tophus (tophi)
M1A.08X0	Idiopathic chronic gout, vertebrae, without tophus (tophi)
M1A.08X1	Idiopathic chronic gout, vertebrae, with tophus (tophi)
M1A.09X0	Idiopathic chronic gout, multiple sites, without tophus (tophi)
M1A.09X1	Idiopathic chronic gout, multiple sites, with tophus (tophi)
M1A.30X0	Chronic gout due to renal impairment, unspecified site, without tophus (tophi)
M1A.30X1	Chronic gout due to renal impairment, unspecified site, with tophus (tophi)
M1A.3110	Chronic gout due to renal impairment, right shoulder, without tophus (tophi)
M1A.3111	Chronic gout due to renal impairment, right shoulder, with tophus (tophi)
M1A.3120	Chronic gout due to renal impairment, left shoulder, without tophus (tophi)
M1A.3121	Chronic gout due to renal impairment, left shoulder, with tophus (tophi)

ICD-10	ICD-10 Description
M1A.3190	Chronic gout due to renal impairment, unspecified shoulder, without tophus (tophi)
M1A.3191	Chronic gout due to renal impairment, unspecified shoulder, with tophus (tophi)
M1A.3210	Chronic gout due to renal impairment, right elbow, without tophus (tophi)
M1A.3211	Chronic gout due to renal impairment, right elbow, with tophus (tophi)
M1A.3220	Chronic gout due to renal impairment, left elbow, without tophus (tophi)
M1A.3221	Chronic gout due to renal impairment, left elbow, with tophus (tophi)
M1A.3290	Chronic gout due to renal impairment, unspecified elbow, without tophus (tophi)
M1A.3291	Chronic gout due to renal impairment, unspecified elbow, with tophus (tophi)
M1A.3310	Chronic gout due to renal impairment, right wrist, without tophus (tophi)
M1A.3311	Chronic gout due to renal impairment, right wrist, with tophus (tophi)
M1A.3320	Chronic gout due to renal impairment, left wrist, without tophus (tophi)
M1A.3321	Chronic gout due to renal impairment, left wrist, with tophus (tophi)
M1A.3390	Chronic gout due to renal impairment, unspecified wrist, without tophus (tophi)
M1A.3391	Chronic gout due to renal impairment, unspecified wrist, with tophus (tophi)
M1A.3410	Chronic gout due to renal impairment, right hand, without tophus (tophi)
M1A.3411	Chronic gout due to renal impairment, right hand, with tophus (tophi)
M1A.3420	Chronic gout due to renal impairment, left hand, without tophus (tophi)
M1A.3421	Chronic gout due to renal impairment, left hand, with tophus (tophi)
M1A.3490	Chronic gout due to renal impairment, unspecified hand, without tophus (tophi)
M1A.3491	Chronic gout due to renal impairment, unspecified hand, with tophus (tophi)
M1A.3510	Chronic gout due to renal impairment, right hip, without tophus (tophi)
M1A.3511	Chronic gout due to renal impairment, right hip, with tophus (tophi)
M1A.3520	Chronic gout due to renal impairment, left hip, without tophus (tophi)
M1A.3521	Chronic gout due to renal impairment, left hip, with tophus (tophi)
M1A.3590	Chronic gout due to renal impairment, unspecified hip, without tophus (tophi)
M1A.3591	Chronic gout due to renal impairment, unspecified hip, with tophus (tophi)
M1A.3610	Chronic gout due to renal impairment, right knee, without tophus (tophi)
M1A.3611	Chronic gout due to renal impairment, right knee, with tophus (tophi)
M1A.3620	Chronic gout due to renal impairment, left knee, without tophus (tophi)
M1A.3621	Chronic gout due to renal impairment, left knee, with tophus (tophi)
M1A.3690	Chronic gout due to renal impairment, unspecified knee, without tophus (tophi)
M1A.3691	Chronic gout due to renal impairment, unspecified knee, with tophus (tophi)
M1A.3710	Chronic gout due to renal impairment, right ankle and foot, without tophus (tophi)
M1A.3711	Chronic gout due to renal impairment, right ankle and foot, with tophus (tophi)
M1A.3720	Chronic gout due to renal impairment, left ankle and foot, without tophus (tophi)
M1A.3721	Chronic gout due to renal impairment, left ankle and foot, with tophus (tophi)
M1A.3790	Chronic gout due to renal impairment, unspecified ankle and foot, without tophus (tophi)

ICD-10	ICD-10 Description
M1A.3791	Chronic gout due to renal impairment, unspecified ankle and foot, with tophus (tophi)
M1A.38X0	Chronic gout due to renal impairment, vertebrae, without tophus (tophi)
M1A.38X1	Chronic gout due to renal impairment, vertebrae, with tophus (tophi)
M1A.39X0	Chronic gout due to renal impairment, multiple sites, without tophus (tophi)
M1A.39X1	Chronic gout due to renal impairment, multiple sites, with tophus (tophi)
M1A.40X0	Other secondary chronic gout, unspecified site, without tophus (tophi)
M1A.40X1	Other secondary chronic gout, unspecified site, with tophus (tophi)
M1A.4110	Other secondary chronic gout, right shoulder, without tophus (tophi)
M1A.4111	Other secondary chronic gout, right shoulder, with tophus (tophi)
M1A.4120	Other secondary chronic gout, left shoulder, without tophus (tophi)
M1A.4121	Other secondary chronic gout, left shoulder, with tophus (tophi)
M1A.4190	Other secondary chronic gout, unspecified shoulder, without tophus (tophi)
M1A.4191	Other secondary chronic gout, unspecified shoulder, with tophus (tophi)
M1A.4210	Other secondary chronic gout, right elbow, without tophus (tophi)
M1A.4211	Other secondary chronic gout, right elbow, with tophus (tophi)
M1A.4220	Other secondary chronic gout, left elbow, without tophus (tophi)
M1A.4221	Other secondary chronic gout, left elbow, with tophus (tophi)
M1A.4290	Other secondary chronic gout, unspecified elbow, without tophus (tophi)
M1A.4291	Other secondary chronic gout, unspecified elbow, with tophus (tophi)
M1A.4310	Other secondary chronic gout, right wrist, without tophus (tophi)
M1A.4311	Other secondary chronic gout, right wrist, with tophus (tophi)
M1A.4320	Other secondary chronic gout, left wrist, without tophus (tophi)
M1A.4321	Other secondary chronic gout, left wrist, with tophus (tophi)
M1A.4390	Other secondary chronic gout, unspecified wrist, without tophus (tophi)
M1A.4391	Other secondary chronic gout, unspecified wrist, with tophus (tophi)
M1A.4410	Other secondary chronic gout, right hand, without tophus (tophi)
M1A.4411	Other secondary chronic gout, right hand, with tophus (tophi)
M1A.4420	Other secondary chronic gout, left hand, without tophus (tophi)
M1A.4421	Other secondary chronic gout, left hand, with tophus (tophi)
M1A.4490	Other secondary chronic gout, unspecified hand, without tophus (tophi)
M1A.4491	Other secondary chronic gout, unspecified hand, with tophus (tophi)
M1A.4510	Other secondary chronic gout, right hip, without tophus (tophi)
M1A.4511	Other secondary chronic gout, right hip, with tophus (tophi)
M1A.4520	Other secondary chronic gout, left hip, without tophus (tophi)
M1A.4521	Other secondary chronic gout, left hip, with tophus (tophi)
M1A.4590	Other secondary chronic gout, unspecified hip, without tophus (tophi)
M1A.4591	Other secondary chronic gout, unspecified hip, with tophus (tophi)

ICD-10	ICD-10 Description
M1A.4610	Other secondary chronic gout, right knee, without tophus (tophi)
M1A.4611	Other secondary chronic gout, right knee, with tophus (tophi)
M1A.4620	Other secondary chronic gout, left knee, without tophus (tophi)
M1A.4621	Other secondary chronic gout, left knee, with tophus (tophi)
M1A.4690	Other secondary chronic gout, unspecified knee, without tophus (tophi)
M1A.4691	Other secondary chronic gout, unspecified knee, with tophus (tophi)
M1A.4710	Other secondary chronic gout, right ankle and foot, without tophus (tophi)
M1A.4711	Other secondary chronic gout, right ankle and foot, with tophus (tophi)
M1A.4720	Other secondary chronic gout, left ankle and foot, without tophus (tophi)
M1A.4721	Other secondary chronic gout, left ankle and foot, with tophus (tophi)
M1A.4790	Other secondary chronic gout, unspecified ankle and foot, without tophus (tophi)
M1A.4791	Other secondary chronic gout, unspecified ankle and foot, with tophus (tophi)
M1A.48X0	Other secondary chronic gout, vertebrae, without tophus (tophi)
M1A.48X1	Other secondary chronic gout, vertebrae, with tophus (tophi)
M1A.49X0	Other secondary chronic gout, multiple sites, without tophus (tophi)
M1A.49X1	Other secondary chronic gout, multiple sites, with tophus (tophi)
M1A.9XX0	Chronic gout, unspecified, without tophus (tophi)
M1A.9XX1	Chronic gout, unspecified, with tophus (tophi)

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC