

Medical Policy

Krystexxa® (pegloticase)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-054
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	<i>Individual Family Plan: All Plans</i> <i>Small Group: All Plans</i> <i>Medicare Advantage: All Plans</i>

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at <http://www.cms.gov> for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Krystexxa® (pegloticase) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Initial coverage for Krystexxa will be provided for 6 months and may be renewed. Continued coverage will be provided for 12 months.

Initial Therapy

Gout, Chronic

1. Krystexxa is prescribed by or in consultation with a rheumatologist or a nephrologist;
AND
2. The patient meets one of the following conditions:

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- a. Patient has had an inadequate response, defined as serum uric acid level that remained > 6 mg/dL following a 3-month trial of at least THREE of the following agents: allopurinol, Uloric, a uricosuric agent.
Note: Examples of uricosuric agents include probenecid, fenofibrate, and losartan; **OR**
- b. Patient has a contraindication or has had an intolerance to a trial of allopurinol, as determined by the prescribing physician; **AND**
3. Patient has current symptoms of gout.
Note: Examples of gout symptoms include gout flares, gout tophus, and gouty arthritis.

Continuation Therapy

Gout, Chronic

1. Krystexxa is prescribed by or in consultation with a rheumatologist or a nephrologist; **AND**
2. Patient is continuing therapy with Krystexxa to maintain response/remission; **AND**
3. Patient has responded to therapy with evidence of serum uric acid level < 6 mg/dL with continued Krystexxa treatments.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Patients with Glucose-6-phosphate dehydrogenase (G6PD) deficiency

BACKGROUND

Krystexxa is a PEGylated uric acid specific enzyme indicated for treatment of chronic gout in adult patients refractory to conventional therapy. It is made up of a recombinant modified mammalian uricase produced by a genetically modified strain of Escherichia coli which is covalently bonded to monomethoxypoly (ethylene glycol) [mPEG].

DEFINITIONS

1. KRYSTEXXA (pegloticase injection), for intravenous infusion Initial U.S. Approval: 2010
 - a. KRYSTEXXA is supplied as a clear, colorless, sterile solution in phosphate buffered saline intended for intravenous infusion after dilution.
 - b. KRYSTEXXA is supplied in a single-dose 2 mL glass vial with a Teflon® coated (latex-free) rubber injection stopper to deliver pegloticase as 8 mg of uricase protein in 1 mL volume.

CODING

Applicable NDC Codes	
75987-0080-10	Krystexxa (pegloticase) injection, solution

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Applicable Procedure Code	
J2507	injection, pegloticase, 1 mg

Applicable ICD-10 Codes	
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.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)
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)

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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)
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)

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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)
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)
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)

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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)

EVIDENCE BASED REFERENCES

1. Krystexxa™ injection for intravenous infusion [prescribing information]. East Brunswick, NJ: Savient Pharmaceuticals; July 2018.

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. February 22, 2022: Annual review – no changes made. February 28, 2023 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 2/28/2023