AmeriHealth Caritas
VIP Care Plus

Medical Policy Bulletin

Title:
Pegloticase (Krystexxa®)
Policy #:
MA08.060g

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

INITIAL THERAPY
Pegloticase (Krystexxa®) is considered medically necessary and, therefore, covered for the treatment of symptomatic chronic gout in adult individuals when all of the following criteria, including dosing and frequency requirements, are met:

- Failure to normalize uric acid levels to less than 6 mg/dL after at least 3 months of one xanthine oxidase inhibitor (XOI) (e.g., allopurinol or febuxostat) at the maximum recommended dose (alone or in combination with probenecid), unless the individual is intolerant to, has had a toxic reaction to, or has a contraindication to taking XOI.
- Individual has at least one of the following:
    - At least two gout flares in the previous 12 months
    - At least one gout tophus
    - Gouty arthritis
- Pegloticase (Krystexxa) must be used in combination with weekly oral methotrexate, unless intolerant, contraindicated, or not clinically appropriate
- Dosing and frequency: 8 mg intravenous (IV) infusion every 2 weeks

CONTINUATION THERAPY
Pegloticase (Krystexxa) is considered medically necessary and, therefore, covered for the continued treatment of symptomatic chronic gout in adult individuals when both of the following are met:

- There is documented improvement in clinical signs and symptoms, such as reduction of uric acid levels to less than 6 mg/dL, gout flare reduction, tophus reduction/resolution, reduction in joint pain/swelling

- Dosing and Frequency: 8 mg IV infusion every two weeks

DOSING AND FREQUENCY REQUIREMENTS

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of pegloticase (Krystexxa). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of pegloticase (Krystexxa) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct post-payment review and audit procedures for any claims submitted for pegloticase (Krystexxa).

EXPERIMENTAL INVESTIGATIONAL

The use of pegloticase (Krystexxa) for non-adults or for individuals with asymptomatic hyperuricemia, is considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of this use cannot be established by review of the available published peer-reviewed literature.

All other uses for pegloticase (Krystexxa) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

When coverage of pegloticase (Krystexxa) is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

Guidelines

There is no Medicare coverage determination addressing pegloticase (Krystexxa); therefore, the Company policy is applicable.

BLACK BOX WARNINGS

Refer to the specific manufacturer's prescribing information for any applicable Black Box Warnings.

The risk of anaphylaxis and infusion reactions is higher in individuals who have lost therapeutic response. Monitor serum uric acid levels prior to infusions and consider discontinuing treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.

BENEFIT APPLICATION

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Subject to the terms and conditions of the applicable Evidence of Coverage, pegloticase (Krystexxa) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria and Dosing and Frequency Requirements listed in this medical policy are met.

However, drugs that are identified in this policy as experimental/investigational are not eligible for coverage or reimbursement by the Company.

Certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when pegloticase (Krystexxa) is covered under a member's medical benefit (Part B benefit). It does not address instances when pegloticase (Krystexxa) is covered under a member's pharmacy benefit (Part D benefit).

DRUG ADMINISTRATION

Pegloticase (Krystexxa) is administered by intravenous infusion; it should not be given as a push or bolus. Pegloticase (Krystexxa) is not recommended for the treatment of asymptomatic hyperuricemia.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Pegloticase (Krystexxa) was approved by the FDA on September 14, 2010, for treatment of individuals with chronic gout that is refractory to conventional therapy.

On July 7, 2022, this indication was updated with the recommendation that pegloticase (Krystexxa) be co-administered with weekly oral methotrexate 15 mg and folic acid or folinic acid supplementation, unless intolerant, contraindicated, or not clinically appropriate.

PEDIATRIC USE

The safety and effectiveness of pegloticase (Krystexxa) in pediatric individuals have not been established.

Description

Pegloticase (Krystexxa) is an intravenously administered uric acid–specific enzyme. It is a recombinant uricase (PEGylated) indicated for the treatment of symptomatic chronic gout in adults (18 years and older) who are refractory to the conventional therapy of xanthine oxidase inhibitors (e.g., allopurinol [Zyloprim] or febuxostat [Uloric]) at the maximum recommended dose, unless intolerant, toxic, or contraindicated. On July 7, 2022, the indication was updated with the recommendation for coadministration with methotrexate, if not contraindicated or not clinically appropriate, due to greater effectiveness compared to pegloticase (Krystexxa) alone (Botson et al., 2023). Pegloticase (Krystexxa) achieves its therapeutic effect by increasing the conversion of uric acid to allantoin, which lowers the serum uric acid level. The allantoin is then excreted by the kidneys.

BACKGROUND OF GOUT

Gout (monosodium urate crystal deposition disease) is a form of arthritis caused by a buildup of plasma uric acid (a by-product of protein metabolism). This uric acid buildup is known as hyperuricemia. There are two categories of hyperuricemia:

- Primary hyperuricemia: lasts indefinitely and occurs in the absence of comorbidities or drugs that alter uric acid production or its excretion.
- Secondary hyperuricemia: excessive urate production or decreased renal function resulting from disease, diet, drug, or toxin.

Individuals diagnosed with gout have usually had hyperuricemia for a considerable amount of time. Many individuals with hyperuricemia have no symptoms (asymptomatic hyperuricemia) for years. Gout manifests acutely with pain, inflammation, swelling, and, possibly, cellulitis. The knees and feet are usual sites of gout flares, but any joint is susceptible. Severe gout flares in the joints of the foot, especially the great toe, are referred to as podagra.

There are four stages of gout:

- Asymptomatic phase: individual has no overt symptoms of gout but does have hyperuricemia and crystalline deposits into tissues.
- Acute gouty arthritis: occurs after years of asymptomatic hyperuricemia.
- Intercritical (interval) gout: there is a gap between flares, but individual is otherwise symptom free and has no joint problems.
- Chronic recurrent and tophaceous (nodules composed of uric acid) gout: after many years of flares, this stage is disabling and involves permanent damage to joints and kidneys.

Gout may manifest as one or more of the following:

- Recurrent acute inflammatory arthritis flares
- Chronic arthropathy
- Formation of tophaceous deposits (urate crystals)
- Uric acid nephrolithiasis
- Chronic nephropathy (due to comorbid states)

Acute gout flares may be treated with dietary changes (eg, decreasing/abstinence from consumption of alcohol, fructose-sweetened drinks, meat, and seafood), non-steroidal anti-inflammatory drugs (NSAID), steroids and colchicine (Colcrys®). Chronic gout treatment usually includes antihyperuricemia medications.

PEER-REVIEWED LITERATURE

SUMMARY
Pegloticase (Krystexxa) Coadministered with Methotrexate

The safety and effectiveness of pegloticase (Krystexxa) was demonstrated in a Phase IV, randomized, double-blind, 52-week study of 152 adults with chronic gout refractory to conventional therapy. Inclusion criteria included baseline serum uric acid (SUA) of at least 7 mg/dL, and inability to maintain SUA less than 6 mg/dL on other urate-lowering therapy, intolerable adverse reactions associated with current urate-lowering therapy, and/or presence of clinically evident tophaceous deposits. Individuals were randomly assigned (2:1) to either pegloticase (Krystexxa) coadministered with weekly oral methotrexate, or pegloticase (Krystexxa) plus placebo. The primary endpoint was the proportion of Month 6 responders (defined as achieving and maintaining serum uric acid less than 6 mg/dL for at least 80% of the time during Month 6). This study reported a statistically significant greater proportion of Month 6 responders who received pegloticase (Krystexxa) coadministered with methotrexate (71%), compared to pegloticase (Krystexxa) plus placebo (38.5%) (P=0.0003).

Pegloticase (Krystexxa) Alone

The safety and effectiveness of pegloticase (Krystexxa) was demonstrated in two replicate, multicenter, randomized, double-blind, placebo-controlled studies. Inclusion criteria included baseline SUA of at least 8 mg/dL, symptomatic gout with at least three gout flares in the previous 18 months or at least one gout tophus or gouty arthritis, and self-reported medical contraindication to allopurinol or medical history of failure to normalize uric acid (to less than 6 mg/dL) with at least 3 months of allopurinol treatment at the maximum medically appropriate dose. The primary endpoint of both studies was the achievement of a plasma uric level of less than 6 mg/dL. Both studies reported a statistically significant lowering of the plasma uric levels (under 6 mg/dL) in those receiving pegloticase (Krystexxa), compared to those receiving placebo.

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or

AmeriHealth Caritas VIP Care Plus

updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)
MEDICALLY NECESSARY
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.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.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.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.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.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.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.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.1110 Lead-induced chronic gout, right shoulder, without tophus (tophi)
M1A.1111 Lead-induced chronic gout, right shoulder, with tophus (tophi)
M1A.1120 Lead-induced chronic gout, left shoulder, without tophus (tophi)
M1A.1121 Lead-induced chronic gout, left shoulder, with tophus (tophi)
M1A.1210 Lead-induced chronic gout, right elbow, without tophus (tophi)
M1A.1211 Lead-induced chronic gout, right elbow, with tophus (tophi)
M1A.1220 Lead-induced chronic gout, left elbow, without tophus (tophi)
M1A.1221 Lead-induced chronic gout, left elbow, with tophus (tophi)
M1A.1310 Lead-induced chronic gout, right wrist, without tophus (tophi)
M1A.1311 Lead-induced chronic gout, right wrist, with tophus (tophi)

M1A.1320 Lead-induced chronic gout, left wrist, without tophus (tophi)
M1A.1321 Lead-induced chronic gout, left wrist, with tophus (tophi)
M1A.1410 Lead-induced chronic gout, right hand, without tophus (tophi)
M1A.1411 Lead-induced chronic gout, right hand, with tophus (tophi)
M1A.1420 Lead-induced chronic gout, left hand, without tophus (tophi)
M1A.1421 Lead-induced chronic gout, left hand, with tophus (tophi)
M1A.1510 Lead-induced chronic gout, right hip, without tophus (tophi)
M1A.1511 Lead-induced chronic gout, right hip, with tophus (tophi)
M1A.1520 Lead-induced chronic gout, left hip, without tophus (tophi)
M1A.1521 Lead-induced chronic gout, left hip, with tophus (tophi)
M1A.1610 Lead-induced chronic gout, right knee, without tophus (tophi)
M1A.1611 Lead-induced chronic gout, right knee, with tophus (tophi)
M1A.1620 Lead-induced chronic gout, left knee, without tophus (tophi)
M1A.1621 Lead-induced chronic gout, left knee, with tophus (tophi)
M1A.1710 Lead-induced chronic gout, right ankle and foot, without tophus (tophi)
M1A.1711 Lead-induced chronic gout, right ankle and foot, with tophus (tophi)
M1A.1720 Lead-induced chronic gout, left ankle and foot, without tophus (tophi)
M1A.1721 Lead-induced chronic gout, left ankle and foot, with tophus (tophi)
M1A.18x0 Lead-induced chronic gout, vertebrae, without tophus (tophi)
M1A.18x1 Lead-induced chronic gout, vertebrae, with tophus (tophi)
M1A.19x0 Lead-induced chronic gout, multiple sites, without tophus (tophi)
M1A.19x1 Lead-induced chronic gout, multiple sites, with tophus (tophi)
M1A.2110 Drug-induced chronic gout, right shoulder, without tophus (tophi)
M1A.2111 Drug-induced chronic gout, right shoulder, with tophus (tophi)
M1A.2120 Drug-induced chronic gout, left shoulder, without tophus (tophi)
M1A.2121 Drug-induced chronic gout, left shoulder, with tophus (tophi)
M1A.2210 Drug-induced chronic gout, right elbow, without tophus (tophi)
M1A.2211 Drug-induced chronic gout, right elbow, with tophus (tophi)
M1A.2220 Drug-induced chronic gout, left elbow, without tophus (tophi)
M1A.2221 Drug-induced chronic gout, left elbow, with tophus (tophi)
M1A.2310 Drug-induced chronic gout, right wrist, without tophus (tophi)
M1A.2311 Drug-induced chronic gout, right wrist, with tophus (tophi)
M1A.2320 Drug-induced chronic gout, left wrist, without tophus (tophi)
M1A.2321 Drug-induced chronic gout, left wrist, with tophus (tophi)
M1A.2410 Drug-induced chronic gout, right hand, without tophus (tophi)
M1A.2411 Drug-induced chronic gout, right hand, with tophus (tophi)
M1A.2420 Drug-induced chronic gout, left hand, without tophus (tophi)
M1A.2421 Drug-induced chronic gout, left hand, with tophus (tophi)
M1A.2510 Drug-induced chronic gout, right hip, without tophus (tophi)
M1A.2511 Drug-induced chronic gout, right hip, with tophus (tophi)
M1A.2520 Drug-induced chronic gout, left hip, without tophus (tophi)
M1A.2521 Drug-induced chronic gout, left hip, with tophus (tophi)
M1A.2610 Drug-induced chronic gout, right knee, without tophus (tophi)
M1A.2611 Drug-induced chronic gout, right knee, with tophus (tophi)
M1A.2620 Drug-induced chronic gout, left knee, without tophus (tophi)
M1A.2621 Drug-induced chronic gout, left knee, with tophus (tophi)
M1A.2710 Drug-induced chronic gout, right ankle and foot, without tophus (tophi)
M1A.2711 Drug-induced chronic gout, right ankle and foot, with tophus (tophi)
M1A.2720 Drug-induced chronic gout, left ankle and foot, without tophus (tophi)
M1A.2721 Drug-induced chronic gout, left ankle and foot, with tophus (tophi)
M1A.28x0 Drug-induced chronic gout, vertebrae, without tophus (tophi)
M1A.28x1 Drug-induced chronic gout, vertebrae, with tophus (tophi)
M1A.29x0 Drug-induced chronic gout, multiple sites, without tophus (tophi)
M1A.29x1 Drug-induced chronic gout, multiple sites, 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.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)

AmeriHealth Caritas
VIP Care Plus

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.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.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.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.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.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.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.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.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.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.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.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.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.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.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

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EXPERIMENTAL INVESTIGATIONAL

E79.0 Hyperuricemia without signs of inflammatory arthritis and tophaceous disease [asymptomatic]

HCPCS Level II Code Number(s)
J2507 Injection, pegloticase, 1 mg

Revenue Code Number(s)
N/A

Policy History

Revisions From MA08.060g:

05/07/2024	This policy has been reissued in accordance with the Company's annual review process.
03/27/2023	This version of the policy will become effective 03/27/2023. The policy was updated in accordance to the changes made by the US Food and Drug Administration (FDA) to address the co-adminstration of pegloticase (Krystexxa) and methotrexate: Pegloticase (Krystexxa) will be used in combination with weekly oral methotrexate , unless intolerant, contraindicated, or not clinically appropriate. The following ICD CM codes have been **deleted** from this policy, due to unspecified laterality: M1A.00x0, M1A.00x1, M1A.0190, M1A.0191, M1A.0290, M1A.0291, M1A.0390, M1A.0391, M1A.0490, M1A.0491, M1A.0590, M1A.0591, M1A.0690, M1A.0691, M1A.0790, M1A.0791, M1A.10x0, M1A.10x1, M1A.1190, M1A.1191, M1A.1290, M1A.1291, M1A.1390, M1A.1391, M1A.1490, M1A.1491, M1A.1590, M1A.1591, M1A.1690, M1A.1691, M1A.1790, M1A.1791, M1A.20x0, M1A.20x1, M1A.2190, M1A.2191, M1A.2290, M1A.2291, M1A.2390, M1A.2391, M1A.2490, M1A.2491, M1A.2590, M1A.2591, M1A.2690, M1A.2691, M1A.2790, M1A.2791, M1A.30x0, M1A.30x1, M1A.3190, M1A.3191, M1A.3290, M1A.3291, M1A.3390, M1A.3391, M1A.3490, M1A.3491, M1A.3590, M1A.3591, M1A.3690, M1A.3691, M1A.3790, M1A.3791, M1A.40x0, M1A.40x1, M1A.4190, M1A.4191, M1A.4290, M1A.4291, M1A.4390, M1A.4391, M1A.4490, M1A.4491, M1A.4590, M1A.4591, M1A.4690, M1A.4691, M1A.4790, M1A.4791

Revisions From MA08.060f:

02/14/2022	This version of the policy will become effective 02/14/2022. This policy was updated to clarify the Company's coverage criteria for Initial Therapy with pegloticase (Krystexxa), in accordance with 2020 American College of Rheumatology Guideline for the Management of Gout (FitzGerald et al). Probenecid was added as an option for prior therapies: one xanthine oxidase inhibitor (XOI) (e.g., allopurinol or febuxostat) at the maximum recommended dose (alone or in combination with probenecid). Coverage criteria for gout flares changed: **FROM:** at least three gout flares in the previous 18 months **TO:** at least two gout flares in the previous 12 months

Revisions From MA08.060e:

03/15/2021	This version of the policy will become effective 03/15/2021.

AmeriHealth Caritas
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	This policy was updated to clarify the Company's coverage criteria for Continuation Therapy. An additional statement was added regarding the risk of anaphylaxis and infusion reactions in those who have lost therapeutic response.

Revisions From MA08.060d:

05/20/2020	This policy has been reissued in accordance with the Company's annual review process.
01/13/2020	This policy has been updated to communicate the Dosing and Frequency requirements for pegloticase (Krystexxa®).

Revisions From MA08.060c:

01/01/2019	This policy was updated to communicate the Company's coverage position for pegloticase (Krystexxa®).

Revisions From MA08.060b:

04/20/2016	This policy has been updated to convey the FDA package insert regarding the lack of studies in the pediatric population.

Revisions From MA08.060a:

01/15/2015	This policy has been updated to include a clinical trial summary and information about potential off-label indications.

Revisions From MA08.060:

01/01/2015	This is a new policy.

Version Effective Date:
03/27/2023
Version Issued Date:
03/27/2023
Version Reissued Date:
05/07/2024