# Krystexxa® (Pegloticase)

**Policy Number**: 2026D0082I
**Effective Date**: November 1, 2026

➲ Instructions for Use

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**Community Plan Policy**
- Krystexxa® (Pegloticase)

**Medicare Advantage Policy**
- Medicare Part B Step Therapy Programs

## Application

### UnitedHealthcare Commercial

This Medical Benefit Drug Policy applies to UnitedHealthcare Commercial benefit plans.

### UnitedHealthcare Individual Exchange

This Medical Benefit Drug Policy applies to Individual Exchange benefit plans.

## Coverage Rationale

➲ See Benefit Considerations

**Krystexxa (pegloticase) is proven for the treatment of chronic gout refractory to conventional therapy.**

**Krystexxa (pegloticase) is medically necessary for the treatment of chronic gout when all of the following criteria are met:**

- For **initial therapy**, **all** of the following:
  - Diagnosis of symptomatic gout as defined by **one** of the following:
    - History of at least 2 gout flares in the previous 12 months; **or**
    - At least 1 gouty tophus; **or**
    - Chronic gouty arthropathy

    **and**
  - History of contraindication, intolerance, or treatment failure (i.e., failure to normalize uric acid to < 6 mg/dL) after 3 months of therapy (at the maximally medically appropriate dose) with **both** of the following: (For Medicare reviews, refer to the CMS section.**)
    - Allopurinol; **and**
    - Febuxostat

    **and**
  - Submission of laboratory values demonstrating baseline serum uric acid level > 6 mg/dL; **and**
  - Prescriber attests that serum uric acid levels will be monitored prior to each infusion and that discontinuation of treatment will be considered if preinfusion levels increase above 6 mg/dL; **and**
  - Prescribed by **one** of the following:


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    - Rheumatologist; **or**
    - Nephrologist

    **and**
  - Krystexxa is initiated and titrated according to U.S. Food and Drug Administration (FDA)–labeled dosing for chronic gout; **and**
  - Initial authorization will be for no more than 12 months
- For **continuation of therapy**, **all** of the following:
  - Patient has previously received treatment with Krystexxa; **and**
  - Patient has experienced a positive clinical response to Krystexxa (e.g., serum uric acid levels < 6 mg/dL, tophus reduction, etc.); **and**
  - Patient has **not** had two consecutive uric acid levels above 6 mg/dL after initiating treatment with Krystexxa; **and**
  - Prescribed by **one** of the following:
    - Rheumatologist; **or**
    - Nephrologist

    **and**
  - Krystexxa is initiated and titrated according to FDA-labeled dosing for chronic gout; **and**
  - Reauthorization will be for no more than 12 months

**Krystexxa (pegloticase) is unproven and not medically necessary for the treatment of asymptomatic hyperuricemia.**

# Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

| HCPCS Code | Description |
|---|---|
| J2507 | Injection, Pegloticase, 1mg |

| Diagnosis Code | 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) |
| 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) |


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| Diagnosis Code | Description |
|---|---|
| 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.10X0 | Lead-induced chronic gout, unspecified site, without tophus (tophi) |
| M1A.10X1 | Lead-induced chronic gout, unspecified site, 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.1190 | Lead-induced chronic gout, unspecified shoulder, without tophus (tophi) |
| M1A.1191 | Lead-induced chronic gout, unspecified 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.1290 | Lead-induced chronic gout, unspecified elbow, without tophus (tophi) |
| M1A.1291 | Lead-induced chronic gout, unspecified 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) |


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| Diagnosis Code | Description |
|---|---|
| M1A.1321 | Lead-induced chronic gout, left wrist, with tophus (tophi) |
| M1A.1390 | Lead-induced chronic gout, unspecified wrist, without tophus (tophi) |
| M1A.1391 | Lead-induced chronic gout, unspecified 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.1490 | Lead-induced chronic gout, unspecified hand, without tophus (tophi) |
| M1A.1491 | Lead-induced chronic gout, unspecified 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.1590 | Lead-induced chronic gout, unspecified hip, without tophus (tophi) |
| M1A.1591 | Lead-induced chronic gout, unspecified 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.1690 | Lead-induced chronic gout, unspecified knee, without tophus (tophi) |
| M1A.1691 | Lead-induced chronic gout, unspecified 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.20X0 | Drug-induced chronic gout, unspecified site, without tophus (tophi) |
| M1A.20X1 | Drug-induced chronic gout, unspecified site, 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.2190 | Drug-induced chronic gout, unspecified shoulder, without tophus (tophi) |
| M1A.2191 | Drug-induced chronic gout, unspecified 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.2290 | Drug-induced chronic gout, unspecified elbow, without tophus (tophi) |
| M1A.2291 | Drug-induced chronic gout, unspecified 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.2390 | Drug-induced chronic gout, unspecified wrist, without tophus (tophi) |
| M1A.2391 | Drug-induced chronic gout, unspecified 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) |


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| Diagnosis Code | Description |
|---|---|
| M1A.2420 | Drug-induced chronic gout, left hand, without tophus (tophi) |
| M1A.2421 | Drug-induced chronic gout, left hand, with tophus (tophi) |
| M1A.2490 | Drug-induced chronic gout, unspecified hand, without tophus (tophi) |
| M1A.2491 | Drug-induced chronic gout, unspecified 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.2590 | Drug-induced chronic gout, unspecified hip, without tophus (tophi) |
| M1A.2591 | Drug-induced chronic gout, unspecified 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.2690 | Drug-induced chronic gout, unspecified knee, without tophus (tophi) |
| M1A.2691 | Drug-induced chronic gout, unspecified 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.2790 | Drug-induced chronic gout, unspecified ankle and foot, without tophus (tophi) |
| M1A.2791 | Drug-induced chronic gout, unspecified 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.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) |


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| Diagnosis Code | Description |
|---|---|
| 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) |
| 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) |


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| Diagnosis Code | Description |
|---|---|
| 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) |
| 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) |

## Background

Pegloticase is a uric acid specific enzyme which is a recombinant uricase and achieves its therapeutic effect by catalyzing the oxidation of uric acid to allantoin, thereby lowering serum uric acid. Allantoin is an inert and water-soluble purine metabolite; it is readily eliminated, primarily by renal excretion.

## Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy.


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# Clinical Evidence

## Proven

### *Chronic Gout*

Pegloticase is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patient's refractory to conventional therapy.

In the phase 4, randomized, double-blind MIRROR trial, 152 adults with uncontrolled gout received pegloticase 8 mg every 2 weeks with either oral methotrexate 15 mg weekly or placebo. At month 6, sustained urate-lowering response occurred in 71.0% of patients receiving methotrexate compared with 38.5% receiving placebo; infusion reactions occurred in 4.2% and 30.6%, respectively. At month 12, response remained higher with methotrexate (60.0% vs 30.8%), and complete resolution of at least one tophus was more frequent among patients with baseline tophi (53.8% vs 31.0%). These findings support the labeled use of methotrexate co-therapy to reduce immunogenicity, improve sustained response, and reduce infusion-reaction risk.

## Professional Societies

### *European League Against Rheumatism (EULAR) 2016 Update*

EULAR published its updated evidence-based recommendations for gout management in 2017, representing a systematic review and update of the 2006 recommendations. The guidelines include the following recommendations:

- Recommended first-line options for acute flare are colchicine (within 12 hours of flare onset) and/or an NSAID (plus a proton pump inhibitor if appropriate), oral corticosteroids, or articular aspiration and injection of corticosteroids.
- In patients with frequent flares and contraindications to colchicine, NSAIDs and corticosteroids (oral and injectable), interleukin-1 (IL-1) blockers should be considered for treating flares. Urate-lowering therapy (ULT) should be adjusted to achieve the uricemia target following IL-1 blocker treatment for flare.
- Prophylaxis is recommended during the first 6 months of ULT. Recommended prophylactic treatment is colchicine, If colchicine is not tolerated or is contraindicated, prophylaxis with NSAIDs at low dosage should be considered.
- ULT is indicated in all patients with recurrent flares, tophi, urate arthropathy and/or renal stones. Initiation of ULT is recommended close to the time of first diagnosis in patients presenting at a young age (< 40 years) or with a very high serum uric acid (SUA) level (> 8.0 mg/dL; 480 µmol/L) and/or comorbidities (renal impairment, hypertension, ischemic heart disease, heart failure).
- In patients with normal kidney function, allopurinol is recommended for first-line ULT, starting at a low dose (100 mg/day), and increasing by 100 mg increments every 2-4 weeks if required, to reach the uricemia target. If the SUA target cannot be reached by an appropriate dose of allopurinol, allopurinol should be switched to febuxostat or a uricosuric or combined with a uricosuric. Febuxostat or a uricosuric are also indicated if allopurinol cannot be tolerated.
- In patients with crystal-proven, severe debilitating chronic tophaceous gout and poor quality of life, in whom the SUA target cannot be reached with any other available drug at the maximal dosage (including combinations), pegloticase is indicated.

### *American College of Rheumatology (ACR) 2020*

In 2020 the ACR published their updated clinical guidelines for the management of gout. ACR recommends:
Recommendations for choice of initial ULT for patients with gout:

- Treatment with allopurinol as the preferred first-line agent, over all other ULTs, is strongly recommended for all patients, including those with moderate-to-severe CKD (stage ≥ 3).
- The choice of either allopurinol or febuxostat over probenecid is strongly recommended for patients with moderate-to-severe CKD (stage ≥ 3).
- The choice of pegloticase as a first-line therapy is strongly recommended against.
- Starting treatment with low-dose allopurinol [≤ 100 mg/day and lower in patients with CKD (stage ≥ 3)] and febuxostat (≤ 40 mg/day) with subsequent dose titration over starting at a higher dose is strongly recommended.
- Starting treatment with low-dose probenecid (500 mg once to twice daily) with subsequent dose titration over starting at a higher dose is conditionally recommended.
- Administering concomitant anti-inflammatory prophylaxis therapy [e.g., colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), prednisone/prednisolone] over no anti-inflammatory prophylaxis therapy is strongly recommended.

When to consider changing ULT strategy:

- Switching to pegloticase over continuing current ULT is strongly recommended for patients with gout for whom XOI treatment, uricosurics, and other interventions have failed to achieve the SU target, and who continue to have


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frequent gout flares (≥ 2 flares/year) or who have non-resolving subcutaneous tophi.
- Switching to pegloticase over continuing current ULT is strongly recommended against for patients with gout for whom XOI treatment, uricosurics, and other interventions have failed to achieve the SU target, but who have infrequent gout flares (< 2 flares/year) and no tophi.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Krystexxa® (pegloticase) is a PEGylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.

Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

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

## Centers for Medicare and Medicaid Services

Coverage guidelines for certain Part B drugs may be found in the Medicare Advantage Medical Policy titled Medications/Drugs (Outpatient/Part B). National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. These NCDs/LCDs/LCAs are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that certain criteria are met, including that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals.

*Preferred therapy criteria for Medicare Advantage members, refer to Medicare Part B Step Therapy Programs.

## References


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4. Richette p et al. 2016 updated EULAR evidence-based recommendations for the management of gout. Ann Rheum Dis. 2017 Jan;76(1):29-42.
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6. Botson JK, Saag K, Peterson J, et al. A randomized, placebo-controlled study of methotrexate to increase response rates in patients with uncontrolled gout receiving pegloticase: primary efficacy and safety findings. *Arthritis Rheumatol.* 2023;75(2):293-304. doi:10.1002/art.42335.
7. Botson JK, Saag K, Peterson J, et al. A randomized, double-blind, placebo-controlled, multicenter efficacy and safety study of methotrexate to increase response rates in patients with uncontrolled gout receiving pegloticase: 12-month findings. *ACR Open Rheumatol.* 2023;5:407-418. doi:10.1002/acr2.11578.




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# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 11/01/2026 | **Template Update**<br>• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans<br>• Added *Application* section to indicate this policy applies to:<br>  ○ UnitedHealthcare Commercial benefit plans<br>  ○ Individual Exchange benefit plans<br>**Supporting Information**<br>• Updated *Clinical Evidence, CMS*, and *References* sections to reflect the most current information<br>• Archived previous policy versions 2025D0082H and IEXD0082.08 |

# Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.


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