



**LivWell**  
INFUSIONS

# Krystexxa Infusion Order

Fax 888 511-7654 Phone 888 864-7341

Patient Name: \_\_\_\_\_  
Patient Phone: \_\_\_\_\_

DOB: \_\_\_\_\_  
SEX: M F

Please Attach All Insurance Information, front and back

## MEDICAL INFORMATION

**Diagnosis:** M1A.9XX1 Chronic Gout, unspecified,  
with tophus

Other \_\_\_\_\_

Patients weight: \_\_\_\_\_

Lab Date: \_\_\_\_\_

Allergies: \_\_\_\_\_

ICD 10: \_\_\_\_\_

*Please see additional pages for other potential ICD-10 codes*

### ALSO INCLUDE...

Clinical/ Progress Notes

Demographics Sheet

Current Medications

Labs

## KRYSTEXXA ORDER

**Patients Weight:** \_\_\_\_\_ kg

**Krystexxa Dose:** 8 mg IV

**Frequency:** Every 2 weeks

\*\*\*Referring office must provide Uric Acid level drawn 24-72 hours prior to each infusion.\*\*\*

**Premeds:** Benadryl 50mg PO Benadryl 50mg IV APAP 500mg PO Methylprednisolone 40mg IV

\*\*\* NOTE: Patient must have an EpiPen/ epinephrine in their possession at each appointment date.\*\*\*

**Date of last Krystexxa Infusions:** \_\_\_\_\_

**Additional Comments:**

## PHYSICIAN INFORMATION

**Referring Physician:** \_\_\_\_\_

**Phone:** \_\_\_\_\_

**Practice Address:** \_\_\_\_\_

**Office Contact:** \_\_\_\_\_

**Fax:** \_\_\_\_\_

**NPI/ TIN:** \_\_\_\_\_

**Referring Physician's Signature** \_\_\_\_\_

**Date:** \_\_\_\_\_

- Patient has previously received treatment with Krystexxa; **and**
- Patient has experienced a positive clinical response to Krystexxa (e.g., serum uric acid levels < 6mg/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
  - Nephrologist**and**
- Krystexxa is initiated and titrated according to US 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.<sup>1</sup>**

## 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.

| HCPSC 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)       |
| M1A.0410       | Idiopathic chronic gout, right hand, without tophus (tophi)           |
| M1A.0411       | Idiopathic chronic gout, right hand, with tophus (tophi)              |

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

| Diagnosis Code | Description   |
|----------------|---|
| M1A.1320       | Lead-induced chronic gout, left wrist, without tophus (tophi)           |
| 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)              |

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

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



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

| Diagnosis Code | Description                                       |
|----------------|---|
| 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 PEGylated product that consists of recombinant modified mammalian urate oxidase (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.

## 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. Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. Refer to the Policy and Procedure addressing the treatment of serious rare diseases.

## 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.

### Professional Societies

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

In 2017 EULAR published their updated recommendations, 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.