CVS/caremark

# PRIOR AUTHORIZATION CRITERIA

| | |
|---|---|
| **BRAND NAME** | **KRYSTEXXA** |
| **(generic)** | **(pegloticase)** |
| ***Status: CVS/caremark Criteria*** | ***MDC*** |
| ***Type: Initial Prior Authorization*** | ***Ref #847-A*** |

**FDA-APPROVED INDICATIONS**

Krystexxa is a pegylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy.[1]

*Limitations of Use:*

Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

**CRITERIA FOR APPROVAL**

| | | | |
|---|---|---|---|
| 1. | Does the patient have a diagnosis of chronic gout?<br>[If no, no further questions.] | Yes | No |
| 2. | Prior to starting Krystexxa therapy, was the patient symptomatic with any of the following clinical features of chronic gout such as tophi, gouty arthropathy, radiographic changes of gout, multiple joint involvement, or associated uric acid nephrolithiasis?<br>[If no, no further questions.] | Yes | No |
| 3. | Will Krystexxa be used concomitantly with oral urate-lowering agents (e.g., allopurinol, Uloric [febuxostat])?<br>[If yes, no further questions.] | Yes | No |
| 4. | Is the request for continuation of therapy?<br>[If no, skip to question 6.] | Yes | No |
| 5. | Has the patient had 2 consecutive uric acid levels less than or equal to 6 mg/dL?<br>[No further questions.] | Yes | No |
| 6. | Has patient had an inadequate response to at least a 3-month trial of a xanthine oxidase inhibitor (i.e., allopurinol or febuxostat) at the medically appropriate maximum dose?<br>[If yes, no further questions.] | Yes | No |
| 7. | Does the patient have a clinical reason for not completing at least a 3-month trial of a xanthine oxidase inhibitor (i.e., allopurinol or febuxostat) at the medically appropriate maximum dose, such as severe allergic reaction, toxicity, intolerance, significant drug interaction, severe or renal dysfunction (for allopurinol only)?<br>[If no, no further questions.] | Yes | No |
| 8. | Has patient had an inadequate response to at least a 3-month trial of probenecid alone or in combination with allopurinol or febuxostat at the medically appropriate maximum dose?<br>[If yes, no further questions.] | Yes | No |
| 9. | Has patient had an inadequate response to at least a 3-month trial of another xanthine oxidase inhibitor (i.e., allopurinol or febuxostat) at the medically appropriate maximum dose?<br>[If yes, no further questions.] | Yes | No |


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| | | | |
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| 10. | Does the patient have a clinical reason for not completing at least a 3-month trial of another xanthine inhibitor (i.e., allopurinol or febuxostat) at the medically appropriate maximum dose, such as severe allergic reaction, toxicity, intolerance, significant drug interaction, severe or renal dysfunction (for allopurinol only)?<br>[If yes, no further questions.] | Yes | No |
| 11. | Does the patient have a clinical reason for not completing at least a 3-month trial of probenecid at the medically appropriate maximum dose such as severe allergic reaction, toxicity, intolerance, known blood dyscrasias or uric acid kidney stones, significant drug interaction, or renal insufficiency (i.e., glomerular filtration rate 30 mL/minute or less)? | Yes | No |

| **Guidelines for Approval** | | | |
|---|---|---|---|
| **Duration of Approval** | | **12 months** | |
| **Set 1:** Continuation therapy | | **Set 2:** Initial therapy, inadequate response to XOI | |
| **Yes to question(s)** | **No to question(s)** | **Yes to question(s)** | **No to question(s)** |
| 1 | 3 | 1 | 3 |
| 2 | | 2 | 4 |
| 4 | | 6 | |
| 5 | | | |
| **Set 3:** Initial therapy, unable to complete 3-month trial of XOI and inadequate response to probenecid | | **Set 4:** Initial therapy, unable to complete 3-month trial of one XOI and inadequate response to second XOI | |
| **Yes to question(s)** | **No to question(s)** | 1 | 3 |
| 1 | 3 | 2 | 4 |
| 2 | 4 | 7 | 6 |
| 7 | 6 | 9 | 8 |
| 8 | | | |
| **Set 5:** Initial therapy, unable to complete 3-month trial of two XOIs | | **Set 6:** Initial therapy, unable to complete 3-month trial of a XOI and probenecid | |
| **Yes to question(s)** | **No to question(s)** | 1 | 3 |
| 1 | 3 | 2 | 4 |
| 2 | 4 | 7 | 6 |
| 7 | 6 | 11 | 8 |
| 10 | 8 | | 9 |
| | 9 | | 10 |

| **Mapping Instructions** | | |
|---|---|---|
| | **Yes** | **No** |
| 1. | Go to 2 | Deny |
| 2. | Go to 3 | Deny |
| 3. | Deny | Go to 4 |
| 4. | Go to 5 | Go to 6 |
| 5. | Approve, 12 months. | Deny |
| 6. | Approve, 12 months | Go to 7 |
| 7. | Go to 8 | Deny |
| 8. | Approve, 12 months | Go to 9 |
| 9. | Approve, 12 months | Go to 10 |
| 10. | Approve, 12 months | Go to 11 |
| 11. | Approve, 12 months | Deny |


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## RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

## REFERENCES


1. Krystexxa [package insert]. East Brunswick, NJ: Savient Pharmaceuticals, Inc.; December 2014.
2. Khanna D, Fitzgerald JD, Khanna PP, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 1: systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. *Arthritis Care Res.* 2012;64(10):1431-1446.
3. Khanna D, Khanna PP, Fitzgerald JD, et al. 2012 American College of Rheumatology guidelines for management of gout. Part 2: therapy and antiinflammatory prophylaxis of acute gouty arthritis. *Arthritis Care Res.* 2012;64(10):1447-1461.
4. Probenecid [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; March 2006.


DOCUMENT HISTORY

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|---|---|
| Written | Specialty Clinical Development (KH) 10/2010 |
| Revised: | KP (adapted from SGM) 10/2012, KR (annual review updates) 11/2012, DK 09/2013, IP 04/2013, IP 09/2014, HY 10/2015, PK 06/2016 , 10/2016 (CMS), PK 07/2017 (CMS) |
| Reviewed: | CDPR: KP 07/2011, 06/2012, LMS 05/2013, SES 04/2014; DNC 05/2015; AA 10/2015, LMS 06/2016 |
| External review: | 9/2011, 08/2012, 07/2013, 07/2014, 07/2015, 06/2016 |


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