HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

PEGLOTICASE (KRYSTEXXA)

Generic	Brand	HICL	GCN	Exception/Other
PEGLOTICASE	KRYSTEXXA	37154		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of symptomatic chronic gout (prior to initiating Krystexxa therapy) with clinical features that may include the following?
   - Tophi
   - Gouty arthropathy
   - Radiographic changes of gout
   - Multiple joint involvement
   - Associated uric acid nephrolithiasis

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's **Krystexxa (pegloticase)** guideline, this medication is only covered when prescribed for symptomatic chronic gout. Your provider did not indicate that you have a diagnosis of symptomatic chronic gout and therefore your request was not approved.

2. Has the provider confirmed that Krystexxa will **NOT** be used concomitantly with oral urate-lowering therapies?

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's **Krystexxa (pegloticase)** guideline, this medication is only covered if your provider confirms you will not be taking Krystexxa at the same time with oral urate-lowering therapies. Your provider did not confirm you will not be taking this medication with oral urate-lowering therapies and therefore your request was not approved.

3. Is the request for a renewal where the patient has had a previous prior authorization for Krystexxa and received at least a three-month supply (i.e., six doses) of Krystexxa with paid claims through the pharmacy or medical benefit within the previous 120 days?

   If yes, continue to #4.
   If no, continue to #5.

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GUIDELINES FOR USE (CONTINUED)

4. Did the provider submit documentation demonstrating that the patient has not had two consecutive uric acid levels above 6mg/dL since starting treatment with Krystexxa?

   If yes, **approve for 6 months by HICL for two 1mL vials (2mL) per 28 days.** Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for Krystexxa has been approved two vials per 28 days for a 6-month period.

   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's **Krystexxa (pegloticase)** guideline, authorization for renewal requires documentation showing that you did not have two consecutive uric acid levels above 6mg/dL since starting treatment with Krystexxa. Your provider **[did not provide this information//or//indicated that you do not meet this criteria]** and therefore your request was not approved.

5. Has the patient had an inadequate response or is there a clinical reason for not completing at least a three-month trial of allopurinol at the medically appropriate maximum dose as defined by **ONE** of the following?
   - The patient experienced a severe allergic reaction to allopurinol
   - The patient experienced toxicity with allopurinol
   - The patient could not tolerate allopurinol
   - The patient's current medication regimen has a significant drug interaction with allopurinol
   - The patient has severe renal dysfunction

   If yes, continue to #6.
   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's **Krystexxa (pegloticase)** guideline, this medication is only covered after you had an inadequate response or there is clinical reason for not completing a 3-month trial with allopurinol at the medically appropriate maximal dose as defined by one of the following:
   - You experienced a severe allergic reaction to allopurinol
   - You experienced toxicity with allopurinol
   - You could not tolerate allopurinol
   - Your current medication regimen has a significant drug interaction with allopurinol
   - You have severe renal dysfunction

   Your provider did not indicate that you previously had a 3-month trial with allopurinol or there is a clinical reason why you cannot try it and therefore your request was not approved.

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PEGLOTICASE (KRYSTEXXA)

GUIDELINES FOR USE (CONTINUED)

6. Has the patient had an inadequate response or is there a clinical reason for not completing at least a three-month trial of febuxostat (Uloric) at the medically appropriate maximum dose as defined by **ONE** of the following?
   - The patient experienced a severe allergic reaction to Uloric (febuxostat)
   - The patient experienced toxicity with Uloric (febuxostat)
   - The patient could not tolerate Uloric (febuxostat)
   - The patient's current medication regimen has a significant drug interaction with Uloric (febuxostat)

   If yes, continue to #7.
   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's **Krystexxa (pegloticase)** guideline, this medication is only covered after you had an inadequate response or there is clinical reason for not completing a 3-month trial with febuxostat (Uloric) at the medically appropriate maximal dose as defined by one of the following:
   - You experienced a severe allergic reaction to Uloric (febuxostat)
   - You experienced toxicity with Uloric (febuxostat)
   - You could not tolerate Uloric (febuxostat)
   - Your current medication regimen has a significant drug interaction with Uloric (febuxostat)

   Your provider did not indicate that you previously had a 3-month trial with febuxostat (Uloric) or there is a clinical reason why you cannot try it and therefore your request was not approved.

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PEGLOTICASE (KRYSTEXXA)

GUIDELINES FOR USE (CONTINUED)

7. Has the patient had an inadequate response or is there a clinical reason for not completing at least a three-month trial of probenecid alone, or in combination with allopurinol or febuxostat, at the medically appropriate maximum dose as defined by **ONE** of the following?
   - The patient experienced a severe allergic reaction to probenecid
   - The patient experienced toxicity with probenecid
   - The patient could not tolerate probenecid
   - The patient has known blood dyscrasias or uric acid kidney stones
   - The patient's current medication regimen has a significant drug interaction with probenecid
   - The patient have severe renal dysfunction (i.e., glomerular filtration rate of 30mL/minute or less)

   If yes, **approve by HICL two 1mL vials (2mL) per 28 days for 6 months.** Please use status code #056 and the approval text provided.
   APPROVAL TEXT: Your request for Krystexxa has been approved two vials per 28 days for a 6-month period.

   If no, do not approve. Please use status code #238 and the denial text provided:
   DENIAL TEXT: Per your health plan's **Krystexxa (pegloticase)** guideline, this medication is only covered after you had an inadequate response or there is clinical reason for not completing a 3-month trial with probenecid alone, or in combination with allopurinol or febuxostat, at the medically appropriate maximal dose as defined by one of the following:
   - You experienced a severe allergic reaction probenecid
   - You experienced toxicity with probenecid
   - You could not tolerate probenecid
   - You have known blood dyscrasias or uric acid kidney stones
   - Your current medication regimen has a significant drug interaction with probenecid
   - You have severe renal dysfunction (i.e., glomerular filtration rate of 30mL/minute or less)

   Your provider did not indicate that you previously had a 3-month trial with probenacid or there is a clinical reason why you cannot try it and therefore your request was not approved.

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PEGLOTICASE (KRYSTEXXA)

RATIONALE
Ensure appropriate utilization of Krystexxa for the treatment of chronic gout.

FDA APPROVED INDICATIONS
Krystexxa is a pegylated uric acid specific enzyme indicated for the treatment of chronic gout in adult patient's refractory to conventional therapy.

REFERENCES

- Krystexxa [package insert]. Bridgewater, NJ: Savient Pharmaceuticals, Inc.; December 2014.
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- 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.
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- Clinical Consult: CVS Caremark Clinical Programs Review. Focus on Rheumatology Clinical Programs. July 2013.
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