J2507

PEGLOTICASE/KRYSTEXXA

FACT SHEET

Description

HCPCS J2507 (Injection, pegloticase, 1mg)

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

Accepted Dosage and Administration

For adult patients, 8mg given as an intravenous infusion every two weeks.

Medical Necessity

Documentation must support compliance with Medicare rules and regulations such as: diagnoses; appropriate orders and signatures; administration/frequency/deliverance of the service; as well as correct coding and billing of the drug, per medical necessity.

Diagnosis must support the above listed condition, refractory to conventional therapy. Pegloticase will be approved when **all** the following conditions are met.

- Baseline serum uric acid of ≥7mg/dl
- Symptomatic gout with at least 3 gout flares in the previous 18 months OR at least 1 gout tophi (sodium urate monohydrate, or uric acid, builds up around your joints) or gouty arthritis
- Patient is currently on NSAIDS or Colchicine or both within last 30 days OR documented intolerance, FDA labeled contraindication or hypersensitivity to both
- Insufficient response uric acid levels > 6mg/dl after at least 3 months of therapy with both allopurinol and febuxostat at maximum tolerated doses unless medically contraindicated. If the patient has well documented medical contraindications, monotherapy will be considered as sufficient.

Intravenous

The following administration details must be documented within the record:

- Documentation to support drug was administered by intravenous route
- Documentation containing location the intravenous injection was administered

Appropriate Signatures

- Signature and credentials of person performing the service must meet CMS requirements
- Amendments/corrections/delayed entries are properly identified

For more information regarding signature requirements, please view the following resources:

- CGS Administrators, LLC, J15 Part B Medical Review https://www.cgsmedicare.com/partb/mr/signatures.html

Supporting Documentation

Documentation of frequency must support accepted prescribing guidelines.

A signed order must be present for the drug by the approved specialty provider or intent to order within the progress note.

Documentation of patient informed consent and agreement for treatment. This should include, but not limited to, the purpose, frequency/dosage, side effects, lab work, monitoring etc.

In addition, a purchase order with the name of the drug and information of the vial should be included.

If applicable, an Advance Beneficiary Notice (ABN) should be included in the record.

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- Signature Tips, https://www.cgsmedicare.com/partb/cert/signatures.pdf
- CMS MLN Fact Sheet, Complying with Medicare Signature Requirements. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/signature_requirements_fact_sheet_icn905364.pdf
- CMS IOM Pub. 100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3.2.4, Signature Requirements. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf

References

- IOM 100-02, Chapter 15 – Covered Medical and Other Health Services, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
- IOM 100-04, Chapter 17 – Drugs and Biologicals, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf
- IOM 100-08, Chapter 3 – Verifying Potential Errors and Taking Corrective Actions, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf
- Notification of Service Specific Post Payment Review for Drugs, https://www.cgsmedicare.com/partb/pubs/news/2020/08/cope18504b.html
- Krystexxa® Prescribing Information package insert:
  - FDA Label, https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/213736s000lbl.pdf
  - Krystexxa® (Horizon Therapeutics USA, Inc.): FDA Package Insert (MedLibrary.org), https://medlibrary.org/lib/rx/meds/krystexxa-1/
  - MagellanRX management℠ Krystexxa® (pegloticase) (Intravenous), https://specialtydrug.magellanprovider.com/media/41060/hne_mrxm_krystexxa_10_20.pdf
  - FDA Supplemental Approval Labeling Letter: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/125293Orig1s104ltr.pdf