Updated: 10/2019
PARP Approved: 11/2019

Prior Authorization Criteria

Depen (penicillamine)

All requests for Depen (penicillamine) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage may be provided with a diagnosis of Wilson's disease and the following criteria is met:

- Diagnosis confirmed by genetic testing or presence of THREE of the following diagnostic features:
  - Presence of Kayser-Fleisher rings
  - Serum ceruloplasmin (CPN) < 20 mg/dL
  - 24-h urine Copper > 40 mcg
  - Liver Biopsy with copper dry weight ≥ 250 mcg/g

- Member must be initiated on copper detoxification unless member has a history of trial and failure, contraindication, or intolerance to Galzin.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:**
  - Three months for initiation of copper detoxification unless the member is unable to take Galzin. In this case, Depen will be approved for 12 months.
- **Reauthorization criteria**
  - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of Cystinuria and the following criteria is met:

- Member must have a history of trial and failure, contraindication, or intolerance to urinary alkalization therapy with potassium citrate
- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with Thiola*
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of Severe, Active Rheumatoid Arthritis and the following criteria is met:

- Member is the age of 18 or older
- Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with methotrexate or another DMARD**.**

- Three-month trial with either Humira* OR Enbrel* with or without MTX
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment
- **Reauthorization Duration of Approval:** 12 months

*Medication may require prior authorization.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

Updated: 10/2019
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Depen (penicillamine)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION	
Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION	
Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION		
Medication:	Strength:	
Frequency:	Duration:	
Is the member currently receiving requested medication? ☐ Yes ☐ No		Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information	
Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:

☐ **Wilson's Disease**

- Was the diagnosis confirmed by genetic testing? ☐ Yes ☐ No
- Was the diagnosis confirmed by any of the following? Please check **all** that apply.
  - ☐ Presence of Kayser-Fleisher rings
  - ☐ Serum ceruloplasmin (CPN) < 20 mg/dL
  - ☐ 24-h urine Copper > 40 mcg
  - ☐ Liver Biopsy with copper
- Has the member met one of the following? Please check **all** that apply.
  - ☐ Initiated on copper detoxification
  - ☐ Has a history of trial and failure, contraindication, or intolerance to Galzin?

☐ **Cystinuria**

- Does the member have a history of trial and failure, contraindication, or intolerance to urinary alkalization therapy with potassium citrate? ☐ Yes ☐ No
- Does the member have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with Thiola? ☐ Yes ☐ No

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Depen (penicillamine)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests)

☐ **Severe, Active Rheumatoid Arthritis**

- Does the member have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with methotrexate or another DMARD? ☐ Yes ☐ No
  If yes, please check **all** that apply.
  - ☐ Methotrexate
  - ☐ Other DMARD: _____
- Has the member had a three-month trial with Humira or Enbrel with or without methotrexate? ☐ Yes ☐ No
  If yes, please check **all** that apply.
  - ☐ Humira
  - ☐ Enbrel

☐ **Other Diagnosis**: _____ ICD-10 Code: _____

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date