Updated: 06/2018
PARP Approved: 07/2018

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.

Drug Name Prior Authorization Criteria:
For all requests for Depen (penicillamine) all of the following criteria must be met:

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
- Member must have a history of trial and failure, contraindication, or intolerance to Xeljanz*
- 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: 06/2018
PARP Approved: 07/2018

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℠ 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 ☐ Cystinuria ☐ Active Rheumatoid Arthritis
☐ Other: _____ ICD-10 Code: _____

Which of the following diagnoses will the medication be used for?

a. ☐ Yes ☐ No Wilson's disease, if yes please answer the following questions:

i. Was the diagnosis confirmed by genetic testing?
☐ Yes ☐ No

ii. Was the diagnosis confirmed by ANY of the following? Please check all the apply:
- Presence of Kayser-Fleisher rings

☐ Yes ☐ No

- Serum ceruloplasmin (CPN) < 20 mg/dL
  ☐ Yes ☐ No

- 24-h urine Copper > 40 mcg
  ☐ Yes ☐ No

- Liver Biopsy with copper dry weight ≥ 250 mcg/g
  ☐ Yes ☐ No

iii. Has the member been initiated on copper detoxification unless member has a history of trial and failure, contraindication, or intolerance to Galzin?
☐ Yes ☐ No

b. ☐ Yes ☐ No Cystinuria, if yes please answer the following questions:

i. Does the member have a history of trial and failure, contraindication, or intolerance to urinary alkalization therapy with potassium citrate?
☐ Yes ☐ No

ii. Does the member have a Member must have a history of trial and failure, contraindication, or intolerance of at least 3 months of treatment with Thiola?
☐ Yes ☐ No

c. ☐ Yes ☐ No Severe, Active Rheumatoid Arthritis, if yes please answer the following questions:

i. Is member 18 years of age or older?
☐ Yes ☐ No

ii. 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

iii. **Does the member have a t**hree-month trial with either Humira* OR Enbrel* with or without MTX?
☐ Yes ☐ No

iv. **Does the m**ember have a history of trial and failure, contraindication, or intolerance to Xeljanz?
☐ Yes ☐ No

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