

Policies Repository



Policy Title Cyclobenzaprine hydrochloride extended-release (Amrix®)

Policy Number FS.CLIN.45

Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.

This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Policy **Cyclobenzaprine hydrochloride extended-release (Amrix®)** is a skeletal muscle relaxant indicated for adjunct treatment to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions.

The use of cyclobenzaprine hydrochloride extended-release (Amrix®) requires prior authorization (ie, clinical pharmacy and/or Medical Director review).

Policy Description **Cyclobenzaprine hydrochloride extended-release (Amrix®)** relieves skeletal muscle spasm of local origin without interfering with muscle function and acts primarily at the brain stem within the central nervous system as opposed to the spinal cord. It Influences both gamma and alpha motor systems by reducing tonic somatic motor activity. The original immediate release formulation of cyclobenzaprine hydrochloride has been available since 1990 and is currently a preferred agent. There have been no clinical studies to demonstrate that the extended release formulation of cyclobenzaprine hydrochloride is more effective than the immediate release version of cyclobenzaprine hydrochloride for muscle spasms.

Policy Guideline Inclusion **Cyclobenzaprine hydrochloride extended-release (Amrix®)** is approved when **all** of the following inclusion criteria are met:

- Documentation of trial and failure with at least 1 week therapy of cyclobenzaprine immediate release containing product
- Documentation of trial and failure with at least 1 week therapy of one of the following drugs:
 - A baclofen containing product
 - A dantrolene containing product
 - A chlorzoxazone containing product
 - A methocarbamol containing product
 - Skelaxin

- A carisoprodol containing product
- A tizanidine containing product

Policy Guideline Exclusion

Cyclobenzaprine hydrochloride extended-release (Amrix®) is denied when **any** of the following exclusion criteria are present:

- No documentation of trial and failure with at least 1 week therapy of cyclobenzaprine immediate release containing product
- No documentation of trial and failure with at least 1 week therapy of one of the following drugs:
 - A baclofen containing product
 - A dantrolene containing product
 - A chlorzoxazone containing product
 - A methocarbamol containing product
 - Skelaxin
 - A carisoprodol containing product
 - A tizanidine containing product

Policy List of Applicable Drugs

| Brand Name | Generic Name |
|------------|------------------------------------------------|
| Amrix | cyclobenzaprine hydrochloride extended-release |

Dosing and Administration

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Policy References

Chou R, Peterson K. Drug Class Review on Skeletal Muscle Relaxants [Final Report] May 2005. Oregon Health & Science University. Drug Effectiveness Review Project [available at <http://www.ohsu.edu/drugeffectiveness/reports/final.cfm>] [The link to this reference is not longer active].

Amrix™ (cyclobenzaprine hydrochloride extended-release capsules). In: Facts and Comparisons [online through Facts and Comparisons Online]. Indy, IN: Walter Kluwer Health Inc. Accessed August 3, 2009.

Amrix™ (cyclobenzaprine hydrochloride extended-release capsules). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed August 3, 2009.

Amrix™ (cyclobenzaprine hydrochloride extended-release capsules) [package insert]. Frazer, PA: Cephalon, Inc.; 2008.

Policy Link to Related Policies

Printed

09/01/2009 10:19:47

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