Market Applicability								
Market	DC	GA	КҮ	MD	NJ	NY	WA	
Applicable	Х	Х	Х	Х	Х	Х	NA	

Equetro (carbamazepine extended-release)

Override(s)	Approval Duration			
Prior Authorization	1 year			
Quantity Limit				

Medications	Quantity Limit
Equetro (carbamazepine extended-release)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Equetro (carbamazepine extended-release) may be approved if the following criteria are met:

- I. Individual is 18 years of age and older; AND
- II. Individual is using to treat acute manic or mixed (DSM 5 Bipolar I specifiers manic or hypomanic episode with mixed features or depressive episode with mixed features) episodes associated with bipolar I disorder; AND
- III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to generic Carbatrol (per label formulated similar to Equetro); AND
- IV. Documentation is provided for the clinical necessity of the brand agents and the same medical reason and clinical benefit are not expected with the generic agents.

OR

- V. Individual is 18 years of age and older; AND
- VI. Individual is using to treat pain associated with trigeminal neuralgia; AND
- VII. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to generically available carbamazepine extended-release (Carbatrol, Tegretol XR); **AND**
- VIII. Documentation is provided for the clinical necessity of the brand agents and the same medical reason and clinical benefit are not expected with the generic agents.

OR

- IX. Individual is using to treat partial seizures with complex symptomatology; OR
- X. Individual is using to treat generalized tonic-clonic seizures; OR
- XI. Individual is using to treat mixed seizures;

AND

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability								
Market	DC	GA	КҮ	MD	NJ	NY	WA	
Applicable	Х	Х	Х	Х	Х	Х	NA	

- XII. Individual has been receiving the requested product for greater than or equal to 90 days;
 - OR
- XIII. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to **one** preferred anticonvulsant; **OR**

<u>Preferred Anticonvulsants</u>: phenobarbital, clonazepam, phenytoin, ethosuximide, epitol, felbamate, clorazepate, diazepam, lamotrigine/lamotrigine ER (all formulations), gabapentin, oxcarbazepine, levetiracetam/levetiracetam XR, zonisamide, acetazolamide, carbamazepine/carbamazepine ER, divalproex sodium, valproic acid, valproate sodium, primidone, roweepra, topiramate, tiagabine

XIV. The preferred agent is not FDA-approved for the prescribed indication and Equetro is.

Note:

Equetro (carbamazepine extended release) has a black box warning for fatal dermatologic reactions, including toxic epidermal necrolysis (TEN) and Stevens - Johnson syndrome (SJS), aplastic anemia, and agranulocytosis. Avoid use of Equetro in patients testing positive for HLA-B* 1502 allele.

Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <u>http://www.clinicalpharmacology.com</u>. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 9, 2020.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE[™] with AHFS[™], Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

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