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CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Zinbryta (daclizumab)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 150 mg per month
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Zinbryta (daclizumab) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

RELAPSING-REMITTING MULTIPLE SCLEROSIS, SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS

For **initial** authorization:

1. Medication must be prescribed by, or in consultation with, or under the guidance of a neurologist; AND
2. Chart notes have been provided confirming diagnosis of Multiple Sclerosis; AND
3. Must have a documented negative TB test (i.e. tuberculosis skin test (PPD), an interferon-release assay (IGRA), or a chest x-ray) within 6 months prior to starting therapy; AND
4. Member has documented trial and failure or contraindication to at least **two** preferred multiple sclerosis agents (two injectable drugs OR two oral drugs OR one injectable and one oral drug).
5. **Dosage allowed:** Subcutaneously 150 mg once monthly.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be retested for TB with a negative result within the past 12 months; AND
2. Member has documented biological response to treatment.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Zinbryta (daclizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Multiple Sclerosis - Clinically isolated syndrome (CIS)

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Zinbryta created. Not covered diagnosis added.

12/06/2017	Confirmation of diagnosis based on McDonald criteria is no longer required.

References:

1. Zinbryta [package insert]. Cambridge, MA; Biogen Inc.: Revised May 2017.
2. Zinbryta. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed June 12, 2017.
3. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology. 2002 Jan;58(2):169-78.
4. Polman CH, Reingold SC, Banwell B, et al. Diagnostic criteria for multiple sclerosis: 2010 Revisions to the McDonald criteria. Annals of Neurology. 2011;69(2):292-302. doi:10.1002/ana.22366.

Effective date: 12/20/2017
Revised date: 12/06/2017