SPECIALTY GUIDELINE MANAGEMENT

ZINBRYTA (daclizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication: Zinbryta is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Zinbryta should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 24 months may be granted for treatment of multiple sclerosis (MS) when both of the following criteria are met:

A. Member has a diagnosis of one of the following relapsing forms of MS:
   1. Relapsing-remitting MS (RRMS)
   2. Progressive-relapsing MS (PRMS)
   3. Secondary progressive MS (SPMS) with documented relapses
B. Member has had an inadequate response to two or more drugs indicated for MS despite adequate duration of treatment

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The following dosing limits apply: 150 mg per 28 days.

V. REFERENCES

1. Zinbryta [package insert]. Cambridge, MA: Biogen, Inc.; May 2016.
2. Kappos L, Wiendl H, Selmaj K, et al. Daclizumab HYP versus interferon beta-1a in relapsing multiple sclerosis. *N Engl J Med*. 2015;373(15):1418-28.
3. Gold R, Giovannoni G, Selmaj K, et al. Daclizumab high-yield process in relapsing-remitting multiple sclerosis (SELECT): a randomised, double-blind, placebo-controlled trial. *Lancet*. 2013;381(9884):2167-75.