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Gateway Health
Prior Authorization Criteria
Zinbryta (daclizumab)

All requests for Zinbryta (daclizumab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Zinbryta (daclizumab) Prior Authorization Criteria:

Coverage may be provided for members 17 years of age or older with a diagnosis of **relapsing forms of multiple sclerosis** (MS) when all of the following criteria is met:

- Documentation of therapeutic failure or an inadequate response to two or more drugs indicated for the treatment of MS **AND**
- Must be prescribed by, or in consultation with, a neurologist or a physician that specializes in the treatment of MS and who is certified through the Zinbryta Risk Evaluation and Mitigation Strategy (REMS) program **AND**
- The drug will not be given in combination with other disease modifying therapies approved for the treatment of MS **AND**
- Attestation by the provider of monitoring and evaluation of serum transaminases (ALT and AST) and bilirubin levels at baseline, monthly and assessed prior to the next dose **AND**
- Attestation by the provider the member does not have evidence of active, severe infection and has recent negative screenings for tuberculosis, Hepatitis B and Hepatitis C **AND**
- Coverage is provided in situations where the member does not have any contraindications including:
    - Pre-existing hepatic disease or hepatic impairment defined as ALT or AST at least two times the ULN **OR**
    - A history of autoimmune hepatitis or other autoimmune condition involving the liver **AND**
- Coverage provided for situations in which there is functional status that can be preserved
    - Member must still either be able to walk at least a few steps or alternatively must have some functional arm/hand use consistent with performing activities of daily living **AND**
- Member, provider and pharmacy must be enrolled in the REMS program **AND**
- The requested dose and frequency should be within FDA approved dosing recommendations and not exceed 150mg/mL once monthly **AND**
- In all situations where coverage is approved, authorizations will be provided for 12 months.

Reauthorization will be required every 12 months demonstrating the following:

- Prescribed by, or in consultation with, a neurologist or a physician that specializes in the treatment of MS and who is certified through the Zinbryta Risk Evaluation and Mitigation Strategy (REMS) program **AND**

- Documentation the member continues to receive benefit from treatment by having the ability to walk at least a few steps or alternatively have some functional arm/hand use consistent with performing activities of daily living **AND**
- Attestation by the provider of monthly monitoring of serum transaminases (ALT and AST) and bilirubin levels **AND**
- Attestation by the provider the member does not have evidence of active, severe infection.

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.