

Clinical Policy: Daclizumab (Zinbryta)

Reference Number: CP.PHAR.269

Effective Date: 08/16

Last Review Date: 08/17

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for daclizumab (Zinbryta™).

Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that Zinbryta is **medically necessary** for the following indications:

I. Initial Approval Criteria

A. Multiple Sclerosis (must meet all):

1. Diagnosis of relapsing-remitting multiple sclerosis (MS);
2. Prescribed by or in consultation with a neurologist;
3. Age \geq 18 years;
4. Failure of one of the following (a or b) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced :
 - a. Tecfidera or Gilenya and any of the following: an interferon-beta agent (*Avonex and Plegridy are preferred agents*), or glatiramer (*Glatopa 20 mg and Copaxone 40 mg are preferred agents*);
 - b. Tecfidera and Gilenya;
5. Member will not use other disease modifying therapies for MS concurrently;
6. Dose does not exceed 150 mg once monthly.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Multiple Sclerosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Status Scale score or reduction in relapses or magnetic resonance imaging lesions);
3. Member is not using other disease modifying therapies for MS concurrently;
4. If request is for a dose increase, new dose does not exceed 150 mg once monthly.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

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1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Daclizumab is a humanized monoclonal antibody. The precise mechanism by which daclizumab exerts its therapeutic effects in multiple sclerosis is unknown but is presumed to involve modulation of interleukin-2 (IL-2) mediated activation of lymphocytes through binding to CD25, a subunit of the high-affinity IL-2 receptor.

Formulations:

Zinbryta is supplied as a sterile, colorless to slightly yellow, clear to slightly opalescent solution for subcutaneous injection containing 150 mg of daclizumab in a single-dose prefilled syringe.

FDA Approved Indication(s):

Zinbryta is a monoclonal antibody/subcutaneous injection indicated for:

- Treatment of adult patients with relapsing forms of multiple sclerosis (MS).

Limitations of use:

- 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.

Safety Information:

Zinbryta is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Zinbryta REMS Program because of the risks of hepatic injury including autoimmune hepatitis, and other immune-mediated disorders.

Appendices

Appendix A: Abbreviation Key

FDA: Food and Drug Administration

MS: multiple sclerosis

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7513	Daclizumab, parenteral, 25 mg

Reviews, Revisions, and Approvals	Date	Approval Date
New policy.	08/16	08/16
Added age requirement. Removed MRI requirement. Updated preferencing to require at least one of the highly effective DMTs on formulary (Tecfidera or Gilenya). Removed contraindications: current tuberculosis or other severe active, pre-existing hepatic disease or impairment/history of autoimmune hepatitis or other autoimmune condition involving the liver, and hypersensitivity. Removed reasons to discontinue.	07/17	08/17

References

1. Zinbryta Prescribing Information. Cambridge, MA: Biogen Inc.; May 2017. Available at <http://www.zinbryta.com>. Accessed June 13, 2017.
2. Olek MJ. Disease-modifying treatment of relapsing-remitting multiple sclerosis. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed June 13, 2017.
3. Olek MJ. Diagnosis of multiple sclerosis in adults. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2017. Available at www.UpToDate.com. Accessed June 13, 2017.
4. Costello K, Halper J, Kalb R, Skutnik L, Rapp R. The use of disease-modifying therapies in multiple sclerosis, principles and current evidence – a consensus paper by the Multiple Sclerosis Coalition. July 2016. Accessed June 13, 2017.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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