# Clinical Policy: Daclizumab (Zinbryta)

Reference Number: CP.PHAR.269
Effective Date: 08.01.16
Last Review Date: 05.18
Line of Business: Medicaid

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Daclizumab (Zinbryta™) is an interleukin-2 receptor blocking antibody.

**FDA Approved Indication(s)**
Zinbryta is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (MS).

Limitation(s) 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.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Zinbryta is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Multiple Sclerosis** (must meet all)**:**

1. Diagnosis of relapsing-remitting MS;
2. Prescribed by or in consultation with a neurologist;
3. Age ≥ 17 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. Zinbryta is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix C*);
6. Dose does not exceed 150 mg per month (1 autoinjector or syringe per month).

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## II. Continued Therapy

**A. Multiple Sclerosis** (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Zinbryta is not prescribed concurrently with other disease modifying therapies for MS (*see Appendix C*);
4. If request is for a dose increase, new dose does not exceed 150 mg per month (1 autoinjector or syringe per month).

**Approval duration: 12 months**

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents;

**B.** Primary progressive MS.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration
MS: multiple sclerosis

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Avonex®, Rebif® (interferon beta-1a) | *Avonex*: 30 mcg IM Q week<br>*Rebif*: 22 mcg or 44 mcg SC TIW | *Avonex*: 30 mcg/week<br>*Rebif*: 44 mcg TIW |
| Plegridy® (peginterferon beta-1a) | 125 mcg SC Q2 weeks | 125 mcg/2 weeks |
| Betaseron®, Extavia® (interferon beta-1b) | 250 mcg SC QOD | 250 mg QOD |
| glatiramer acetate (Copaxone®, Glatopa®) | *Copaxone*: 20 mg SC QD or 40 mg SC TIW | *Copaxone*: 20 mg/day or 40 mg TIW |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| | *Glatopa*: 20 mg SC QD | *Glatopa*: 20 mg/day |
| Gilenya™ (fingolimod) | 0.5 mg PO QD | 0.5 mg/day |
| Tecfidera® (dimethyl fumarate) | 120 mg PO BID for 7 days, followed by 240 mg PO BID | 480 mg/day |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: General Information*

- Disease-modifying therapies for MS are: daclizumab (Zinbryta®), glatiramer acetate (Copaxone®, Glatopa®), interferon beta-1a (Avonex®, Rebif®), interferon beta-1b (Betaseron®, Extavia®), peginterferon beta-1a (Plegridy®), dimethyl fumarate (Tecfidera®), fingolimod (Gilenya™), teriflunomide (Aubagio®), alemtuzumab (Lemtrada®), mitoxantrone (Novantrone®), natalizumab (Tysabri®), and ocreliuzmab (Ocrevus™).
- Because of the risks of hepatic injury, including autoimmune hepatitis, and other immune-mediated disorders, Zinbryta is available only through a restricted distribution program called the Zinbryta REMS Program.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Relapsing MS | 150 mg SC once monthly | 150 mg/month |

## VI. Product Availability

Single-dose prefilled autoinjector or syringe: 150 mg/mL

## VII. References

1. Zinbryta Prescribing Information. Cambridge, MA: Biogen Inc.; August 2017. Available at http://www.zinbryta.com. Accessed January 5, 2018.
2. 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. March 2017. Accessed January 5, 2018.

## 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 | P&T 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 |
| 2Q 2018 annual review: no significant changes; modified age restriction from ≥ 18 years to ≥ 17 years per prescribing information; references reviewed and updated. | 01.05.18 | 05.18 |

**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.

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.

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**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.