

Clinical Policy: Daclizumab (Zinbryta)

Reference Number: ERX.SPA.120

Effective Date: 10.01.16

Last Review Date: 05.18

[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 Envolve Pharmacy Solutions™ 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 \geq 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 (*Betaseron and Rebif are preferred agents*), glatiramer (*Glatopa 20 mg and Copaxone 40 mg are preferred agents*), or Aubagio;
 - 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).

**Prior authorization is required for these agents*

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions 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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Avonex [®] , Rebif [®] (interferon beta-1a)	Avonex: 30 mcg IM Q week Rebif: 22 mcg or 44 mcg SC TIW	Avonex: 30 mcg/week 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 Glatopa: 20 mg SC QD	Copaxone: 20 mg/day or 40 mg TIW Glatopa: 20 mg/day
Aubagio [®] (teriflunomide)	7 mg or 14 mg PO QD	14 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 ocrelizumab (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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.16	09.16
Converted to new template. Added age requirement as safety and efficacy have not been established in pediatric populations. Removed MRI requirement as it is a non-specific diagnostic test (plus, specialist involvement in care is required). Updated preferencing to require at least one of the highly effective DMTs on formulary (Tecfidera or Gilenya). Added PPMS as a diagnosis not covered.	06.17	08.17
2Q 2018 annual review: No significant changes. Modified age 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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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