envolve Pharmacy Solutions

Clinical Policy: Daclizumab (Zinbryta)
Reference Number: ERX.SPA.120
Effective Date: 10.01.16
Last Review Date: 08.17
Line of Business: Commercial [Prescription Drug Plan] 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
Zinbryta is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (MS).

Limitation 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 (which may include office chart notes and lab results) 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 ≥ 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 *(Betaseron and Rebif are preferred agents)*, glatiramer *(Glatopa 20 mg and Copaxone 40 mg are preferred agents)*, or Aubagio;
   b. Tecfidera and Gilenya;
5. Member will not use other disease modifying therapies for MS concurrently;
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 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 (e.g., improved or maintained disease control evidenced by decreased or stabilized Expanded Disability Status Scale (EDSS) score or reduction in relapses or MRI 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 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
EDSS: Expanded Disability Status Scale
FDA: Food and Drug Administration
MS: multiple sclerosis
MRI: magnetic resonance imaging

Appendix B: Therapeutic Alternatives

Drug	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
Copaxone®, Glatopa® (glatiramer acetate)	*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

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.; 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.

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

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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