Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date:05/01/2019**
Policy Number: PA.CP.PHAR.269	**Effective Date: 01/2018** **Revision Date: 04/2019**
Policy Name: Daclizumab (Zinbryta)	**HC Approval Date:**

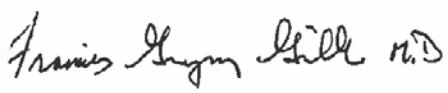
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired: drug is no longer on the market.

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Daclizumab (Zinbryta)

Reference Number: PA.CP.PHAR.269
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

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

Policy/Criteria
It is the policy Pennsylvania Health and Wellness® that Zinbryta is **medically necessary** for the following indications:

I. Initial Approval Criteria

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

1. Diagnosis of a relapsing form of multiple sclerosis (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. 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 PA.CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.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
Retire, drug is no longer on the market.	4/19	

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.