Zinbryta (daclizumab)

DRUG.00089

Overrides	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Zinbryta (daclizumab) solution for injection	May be subject to quantity limit

APPROVAL CRITERIA

I. Requests for Zinbryta (daclizumab) may be approved for the single-agent treatment of individuals with relapsing-remitting multiple sclerosis (RRMS) who meet **all** of the following criteria:

   A. Individual is 18 years of age and older; **AND**

   B. Individual has received prior treatment with **at least two** alternative drug therapies indicated for the treatment of multiple sclerosis (for example, interferons, glatiramer) and failed to achieve an adequate response to those therapies.

Requests for Zinbryta (daclizumab) may **not** be approved when the above criteria are not met and for all other indications including, but not limited to:

1. Primary progressive multiple sclerosis (PPMS);
2. Secondary progressive multiple sclerosis (SPMS);
3. Combination treatment with other disease modifying biologic MS drug therapies (for example, interferons, Glatiramer, alemtuzumab, natalizumab and ocrelizumab);
4. Individuals with hepatic disease, hepatic impairment and autoimmune conditions involving the liver.

Notes:

Black box warnings from the FDA PI Label (2017) include the following:

- Zinbryta can cause severe liver injury including life-threatening events, liver failure, and autoimmune hepatitis.
- Zinbryta is contraindicated in patients with pre-existing hepatic disease, hepatic impairment or autoimmune conditions involving the liver.
- Immune-mediated disorders can occur with Zinbryta.
- Due to the risks of hepatic injury including autoimmune hepatitis, and other immune-mediated disorders, Zinbryta is available only through a Risk Evaluation Mitigation Strategy (REMS) restricted distribution program.

Additional warnings and recommendations from the FDA PI Label (2017) include:

- The most common adverse reactions to Zinbryta include: nasopharyngitis, upper respiratory tract infection, rash, influenza, dermatitis, oropharyngeal pain, bronchitis, eczema, and lymphadenopathy.
- Administration of vaccinations during, and up to 4 months following, treatment with Zinbryta is not recommended.
- Zinbryta may cause depression-related events.
- Prior to, and throughout treatment with Zinbryta (every 6 months), monitor serum transaminases (ALT and AST) and total bilirubin levels for evidence of hepatic dysfunction.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Daclizumab. In: DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated September 7, 2017. Available at: http://www.micromedexsolutions.com. Accessed on September 30, 2017.
2. Daclizumab Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised March 19, 2017. Accessed on September 29, 2017.
3. Tramacere I, Giovane C, Salanti G, et al. Immunomodulators and immunosuppressants for relapsing-remitting multiple sclerosis: a network meta-analysis. Cochrane Database Syst Rev. 2015;(2):CD011381.
4. Zenapax®.[Product Information]. Hoffmann-La Roche Inc., Nutley, NJ; September 15, 2005. Available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/103749s5059lbl.pdf. Accessed on September 30, 2017.
5. Zinbryta® .[Product Information]. Biogen Inc., Cambridge, MA; August 28, 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761029s007lbl.pdf. Accessed on September 30, 2017.