Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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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:

I. Primary progressive multiple sclerosis (PPMS);
II. Secondary progressive multiple sclerosis (SPMS);
III. Combination treatment with other disease modifying biologic MS drug therapies (for example, interferons, Glatiramer, alemtuzumab, natalizumab and ocrelizumab);
IV. 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.

Market Applicability															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	N/A

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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:

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