



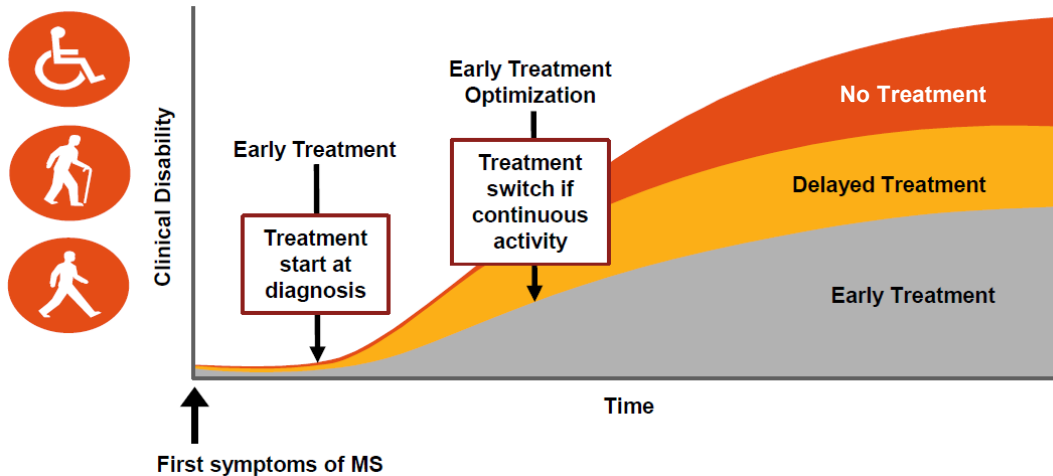
Therapeutic Benefits and Risks of Disease Modifying Therapies for MS

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DMT Treatment Goals

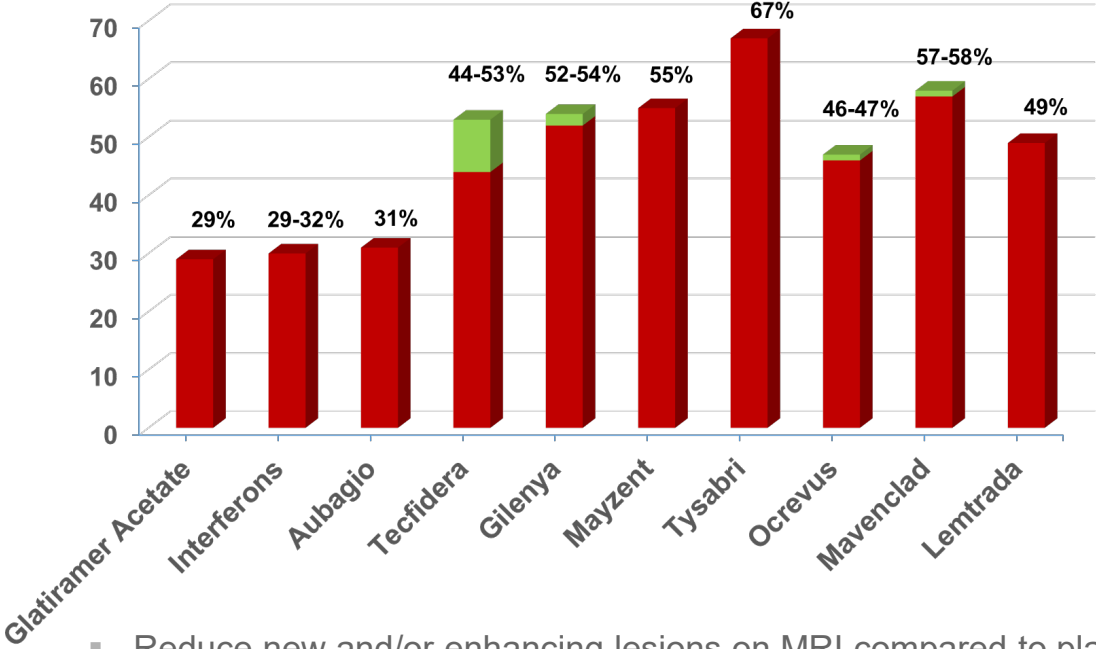
- DMT: Disease Modifying Therapy
- NEDA: No Evidence of Disease Activity
- Progressive MS: NEDA, slow disability progression



Adapted from: Ziemssen T, et al. J Neurol. 2016

Effectiveness of DMT

Percent Reduction in Relapse Rates



- Reduce new and/or enhancing lesions on MRI compared to placebo

Self-Injectable DMT

Rebif Rebidose[®], Avonex[®],
Betaseron[®], Extavia[®], Plegridy[®]

Common Side Effects:

- Injection-site reactions
- Flu-like symptoms

Less Common Side Effects:

- Depression
- Thyroid abnormalities
- Blood count or liver abnormalities

Monitoring: blood count, liver function test, thyroid function

Copaxone[®], Glatopa[®], Glatiramer
Acetate (Mylan[®])

Maximum effectiveness after 6-12 months

Common Side Effects:

- Injection-site reactions
- Lipoatrophy

Less Common Side Effects:

- Immediate post-injection reactions (chest pain, shortness of breath, anxiety, palpitations, flushing)
- Chest pain

Monitoring: none

Tecfidera[®] Family (Fumarates)

Oral Capsules

Tecfidera[®], Dimethyl Fumarate, Vumerity[®], Bafiertam[®]

Common Side Effects:

- GI: nausea, heart burn, stomach pain, diarrhea, vomiting
- Flushing: redness, heat, itching, rash

Less Common Side Effects:

- Abnormal liver tests
- Low lymphocytes
- PML

Risk factors for PML:

older age, low lymphocytes

Monitoring: blood count, liver function test



Gilenya[®] Family (S1PRs)

Oral Tablets

Gilenya[®], Mayzent[®], Zeposia[®]

Common Side Effects

- Headache
- Diarrhea
- Back pain
- Abnormal liver tests
- Low lymphocytes (expected)

Less Common Side Effects

- Low heart rate, AV block
- Herpes viral infection
- Macular edema
- Skin cancers
- PML
- Rebound syndrome

Monitoring

Baseline – blood count, liver function test, ECG, HbA1c, Varicella zoster antibody, OCT eye exam, CYP2C9 genetic test (Mayzent), First-dose observation (FDO)

Routine – blood count, liver function test, OCT eye exam 3-4 months after starting medication

Aubagio® (Teriflunomide)

Oral Tablet

Common Side Effects

- Hair thinning, hair loss
- GI: diarrhea, nausea
- Abnormal liver tests

Less Common Side Effects

- Low lymphocytes
- Liver Injury
- Numbness, tingling
- Increased blood pressure
- Severe allergic reactions

Monitoring: blood count, liver function test, blood pressure

Other Considerations: Long half-life

**FDA Warning:
Liver Toxicity**

**FDA Warning:
Fetal Toxicity**

Tysabri® (natalizumab)

IV Infusion

Common Side Effects

- Infusion reactions
- Respiratory infections

Less Common Side Effects

- Rebound syndrome
- **PML**

Risk Factors for PML

- JC Virus antibody positive
- Longer duration of treatment
- Previous immunosuppressant therapy

FDA Monitoring Program (REMS)

- JC Virus Antibody Monitoring
- Report any cases of PML



Ocrevus[®] (ocrelizumab)

IV Infusion

Effectiveness for Primary Progressive MS

- Patients taking Ocrevus were 24% less likely to have confirmed disability progression compared to placebo

Common Side Effects

- Infusion reactions
- Increased infections

Less Common Side Effects

- Low antibody levels
- Hepatitis B reactivation
- PML

Monitoring:

blood count, antibody levels

Second Line Disease Modifying Therapies

Mavenclad® (cladribine)

Common Side Effects:

- Respiratory infections
- Low lymphocytes

Less Common Side Effects:

- Liver toxicity
- Herpes infections
- Cancer

**FDA Warning:
Fetal Toxicity**

Lemtrada® (alemtuzumab)

FDA Monitoring Program (REMS)

- Monthly monitoring up to 4-years after stopping medication

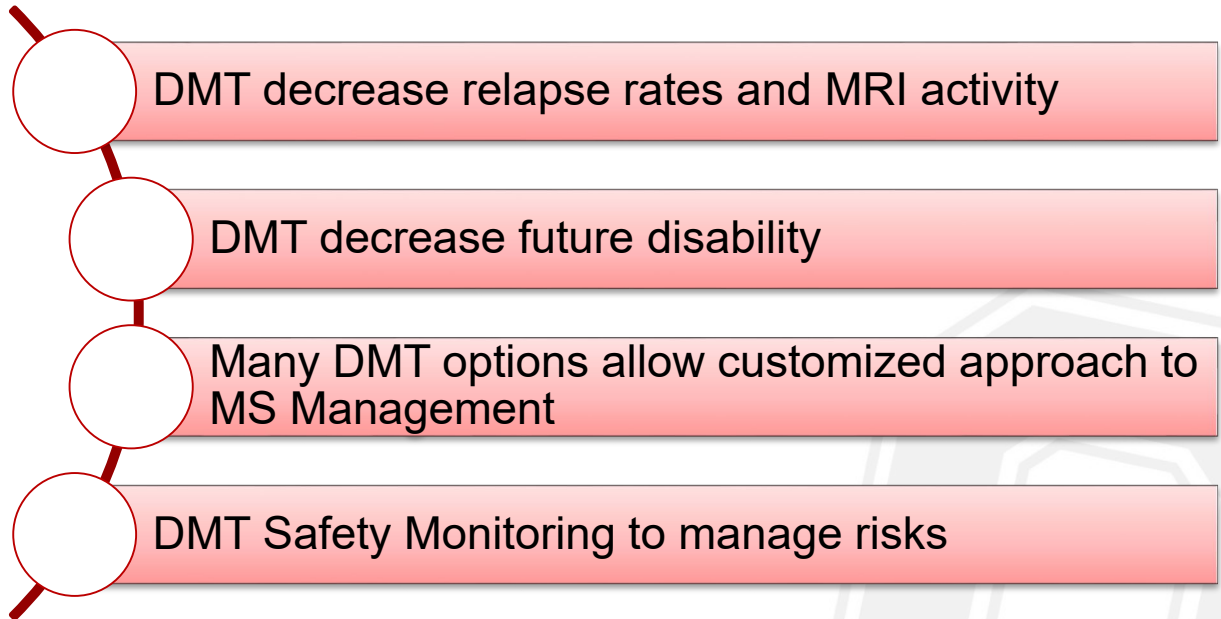
Warnings

- Infusion reactions
- Autoimmune disorders
- Cancer
- Stroke

Serious Side Effects:

- Increased infections
- Liver injury

Balancing the Benefits and the Risks of DMT





Thank You

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