# APPROVED LONG-TERM TREATMENTS FOR MS

### **Self-Injected Medications**

NAME AND TYPE OF DRUG	SIDE EFFECTS	HOW ADMINISTERED	ADDITIONAL NOTES
Avonex® (Interferon beta-1a) immune system modulator with antiviral properties	Flu-like symptoms and headache, blood count and liver test abnormalities	30 micrograms taken via weekly intermuscular injection	Side effects may be prevented and/or managed effectively through various treatment strategies; side effect problems are usually temporary. Blood tests may be given periodically to monitor liver enzymes, blood-cell counts, and neutralizing antibodies.
Betaseron® (Interferon beta-1b) immune system modulator with antiviral properties	Flu-like symptoms, injection-site skin reaction, blood count and liver test abnormalities	250 micrograms taken via subcutaneous injection every other day	Side effects may be prevented and/or managed effectively through various treatment strategies; side effect problems are usually temporary. Blood tests may be given periodically to monitor liver enzymes, blood-cell counts, and neutralizing antibodies.
Copaxone® (glatiramer acetate) Synthetic chain of four amino acids found in myelin (immune system modulator that blocks attacks on myelin)	Injection-site skin reaction as well as an occasional systemic reaction - occurring at least once in approximately 10 percent of those tested	20 (daily) or 40 (three times weekly) milligrams taken via subcutaneous injection	Systemic reactions occur about five to 15 minutes following an injection and may include anxiety, flushing, chest tightness, dizziness, palpitations, and/or shortness of breath. Usually lasting for only a few minutes, these symptoms do not require specific treatment and have no long-term negative effects. Copaxone was originally approved at a dose of 20 milligrams daily, but in January 2014, a new dose of 40 milligrams three times weekly was approved by the FDA. The original 20-milligram daily dose remains available, so patients and their doctors may now choose their preferred dosing regimen.
Extavia® (Interferon beta- 1b) immune system modulator with antiviral properties	Flu-like symptoms, injection-site skin reaction, blood count and liver test abnormalities	250 micrograms taken via subcutaneous injection every other day	Side effects may be prevented and/or managed effectively through various treatment strategies; side effect problems are usually temporary. Blood tests may be given periodically to monitor liver enzymes, blood-cell counts, and neutralizing antibodies.

### **Self-Injected Medications**

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Glatopa™ (glatiramer acetate) As a generic version of Copaxone, Glatopa is a synthetic chain of four amino acids found in myelin (immune system modulator that blocks attacks on myelin)	Using study results from trials with Copaxone, side effects include injection-site skin reaction as well as an occasional systemic reaction - occurring at least once in pproximately 10 percent of those tested with Copaxone	20 milligrams taken daily via subcutaneous injection	Using study results from trials with Copaxone, systemic reactions occur about five to 15 minutes following an injection and may include anxiety, flushing, chest tightness, dizziness, palpitations, and/or shortness of breath. Usually lasting for only a few minutes, these symptoms do not require specific treatment and have no long-term negative effects.
Plegridy® (Interferon beta- 1a) immune system modulator with antiviral properties	Flu-like symptoms, injection-site skin reaction, blood count and liver test abnormalities	125 micrograms taken via subcutaneous injection once every two weeks	Side effects may be prevented and/or managed effectively through various treatment strategies; side effect problems are usually temporary. Blood tests may be given periodically to monitor liver enzymes, blood-cell counts, and neutralizing antibodies.
Rebif® (Interferon beta- 1a) immune system modulator with antiviral properties	Flu-like symptoms, injection-site skin reaction, blood count and liver test abnormalities	44 micrograms taken via subcutaneous injection three times weekly	Side effects may be prevented and/or managed effectively through various treatment strategies; side effect problems are usually temporary. Blood tests may be given periodically to monitor liver enzymes, blood-cell counts, and neutralizing antibodies.
Zinbryta™ (daclizumab) Genetically engineered monoclonal antibody that binds to CD25, a receptor on T cells that is thought to become activated in response to MS.	Side effects include cold symptoms, upper-respiratory-tract infection, rash, influenza, throat pain, eczema, enlargement of lymph nodes, depression, and increased liver.	150 milligrams taken via subcutaneous injection once per month	Zinbryta has a boxed warning stating that the drug can cause severe liver injury and monthly blood tests to monitor the patient's liver function are required. Other risks include: immune conditions, hypersensitivity reactions (anaphylaxis or angioedema), increased risk of infections, and depression and/or suicidal ideation. Zinbryta should be used only in patients who have had an inadequate response to two or more MS drugs.

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#### **Infused Medications**

NAME AND TYPE OF DRUG	SIDE EFFECTS	HOW ADMINISTERED	ADDITIONAL NOTES
Lemtrada® (alemtuzumab) Humanized monoclonal antibody that rapidly depletes or suppresses immune system cells (T and B cells), which can damage the myelin and nerves of the central nervous system (CNS).	Common side effects include rash, itching, headache, pyrexia (increase in temperature), nasopharyngitis (inflammation of the nose and throat), nausea, diarrhea and vomiting, insomnia, numbness/tingling, dizziness, pain, flushing, and infection.	Lemtrada is given for a course of five days via intravenous (IV) infusion and followed one year later by a second three-day course.	Adverse events from Lemtrada can include infusion reactions to the medication, an increased risk of infection, emergent autoimmune diseases, a potentially severe bleeding disorder called immune thrombocytopenic purpura (ITP), and an increased risk of malignancies including thyroid cancer, melanoma and lymphoproliferative disorders. For early detection and management of these risks, Lemtrada is only available through a restricted distribution program, the Lemtrada REMS (Risk Evaluation and Mitigation Strategy).
Novantrone® (mitoxantrone) Antineoplastic agent (immune system modulator and suppressor)	Side effects include nausea, thinning hair, loss of menstrual periods, bladder infections, and mouth sores; additionally, urine and whites of the eyes may turn a bluish color temporarily	IV infusion once every three months (for two to three years maximum)	Novantrone carries the risk of cardiotoxicity (heart damage) and leukemia; it may not be given beyond two or three years. People undergoing treatment must have regular testing for cardiotoxicity, white blood cell counts, and liver function. Because of the potential risks, Novantrone is seldom prescribed for individuals with MS. Anyone taking Novantrone now or given Novantrone previously needs to have annual evaluations of his or her heart function, even if no longer receiving this medication.
Tysabri® (natalizumab) Humanized monoclonal antibody (inhibits adhesion molecules; thought to prevent damaging immune cells from crossing the blood-brain barrier)	Headache, fatigue,depression, joint pain, abdominal discomfort, and infection	IV infusion every four weeks	Risk of infection (including pneumonia) was the most common serious adverse event during the studies (occurring in a small percentage of patients). The TOUCH Prescribing Program monitors patients for signs of PML, an often-fatal viral infection of the brain. Risk factors for PML include: the presence of JC virus antibodies, previous treatment with immunosuppressive drugs, and taking Tysabri for more than two years.

#### **Oral Medications**

NAME AND TYPE OF DRUG	SIDE EFFECTS	HOW ADMINISTERED	ADDITIONAL NOTES
Aubagio® (teriflunomide) Immunomodulator (affecting the production of T and B cells; may also inhibit nerve degeneration)	Headache, elevations in liver enzymes, hair thinning, diarrhea, nausea, neutropenia (a condition that reduces the number of certain white blood cells), and paresthesia (tingling, burning, or numbing sensation)	7- or 14- milligram tablet taken orally, once per day	More severe adverse events include the risk of severe liver injury and the risk of birth defects if used during pregnancy. A TB test and blood tests for liver function must be performed within six months prior to starting Aubagio, and liver function must be checked regularly. If liver damage is detected, or if someone becomes pregnant while taking this drug, accelerated elimination of the drug is prescribed.
Gilenya® (fingolimod, FTY720) S1P-receptor modulator (blocks potentially damaging T cells from leaving lymph nodes)	Headache, flu, diarrhea, back pain, abnormal liver tests and cough	0.5-milligram capsule taken orally once per day	Adverse events include: a reduction in heart rate (dose-related and transient); infrequent transient AV conduction block of the heart; a mild increase in blood pressure; macular edema (a condition that can affect vision, caused by swelling behind the eye); reversible elevation of liver enzymes; and a slight increase in lung infections (primarily bronchitis). Infections, including herpes infection, are also of concern. A six-hour observation period is required immediately after the first dose, to monitor for cardiovascular changes.
Tecfidera® (dimethyl fumarate) Immunomodulator with anti- inflammatory properties; may have neuroprotective effects, potentially protecting the nerves and myelin covering from damage	Flushing and gastrointestinal events; reduced white-blood cell (lymphocyte) counts; elevated liver enzymes in small percentage of patients	240-milligram tablet taken twice daily	Other adverse events include mild or moderate upper respiratory infection, pruritus (chronic itching), and erythema (skin redness or rash). In studies, the only serious adverse events to occur in two or more patients taking Tecfidera was gastroenteritis (an inflammation of the lining of the intestines) and gastritis (an inflammation of the stomach lining). Reduced white-blood cell (lymphocyte) counts were seen during the first year of treatment. Liver enzymes were elevated in 6 percent of individuals taking Tecfidera, compared to 3 percent on placebo.