

# APPROVED LONG-TERM TREATMENTS FOR MS: Self-Injected Medications

| NAME AND TYPE OF DRUG  | SIDE EFFECTS  | HOW ADMINISTERED  | ADDITIONAL NOTES   |
|--|---|---|--|
| <b>Avonex</b><br>(Interferon beta-1a)<br>immune system modulator with antiviral properties   | Flu-like symptoms and headache  | 30 micrograms taken via weekly intramuscular 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.   |
| <b>Betaseron</b><br>(Interferon beta-1b)<br>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.   |
| <b>Copaxone</b><br>(glatiramer acetate)<br>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 mg daily, but in January 2014, a new dose of 40 mg three-times weekly was approved by the FDA. The original 20-mg daily dose remains available, so patients and their doctors may now choose their preferred dosing regimen. |
| <b>Extavia</b><br>(Interferon beta-1b)<br>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.   |
| <b>Glatopa</b><br>(glatiramer acetate)<br>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 approximately 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.  |
| <b>Plegridy</b><br>(Interferon beta-1a)<br>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.   |
| <b>Rebif</b><br>(Interferon beta-1a)<br>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.   |

SELF-INJECTED MEDICATIONS

# APPROVED LONG-TERM TREATMENTS FOR MS: Infused and Oral Medications

| NAME AND TYPE OF DRUG |  | SIDE EFFECTS   | HOW ADMINISTERED  | ADDITIONAL NOTES  |
|-----------------------|--|--|---|---|
| INFUSED MEDICATIONS   | <b>Lemtrada</b><br>(alemtuzumab)<br>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).   |
|                       | <b>Novantrone</b><br>(mitoxantrone)<br>Antineoplastic agent (immune system modulator and suppressor)   | Usually well tolerated; 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 3 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.   |
|                       | <b>Tysabri</b><br>(natalizumab)<br>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      | <b>Aubagio</b><br>(teriflunomide)<br>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 numbness 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.   |
|                       | <b>Gilenya</b><br>(fingolimod, FTY720)<br>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.                      |
|                       | <b>Tecfidera</b><br>(dimethyl fumarate)<br>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 mg 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. |