The MS Disease-Modifying Medications

National
Multiple Sclerosis
Society

Current as of January 2015. This online brochure is updated with breaking news as required. If you have a printed a copy of this publication, please check **nationalMSsociety.org/DMD** to assure that you have the most current edition.

For some people, a diagnosis of MS is a relief, giving a name and a reason for a parade of strange symptoms. For others, a diagnosis of MS brings images of the worst possible future. Both reactions will likely change somewhat over time, but for many with MS, diagnosis is a day when life changes.

Even before the news can be fully absorbed, people with MS face a decision about taking a disease-modifying medication. Based on data from clinical studies, the National MS Society's National Medical Advisory Committee emphasizes that disease-modifying medications are most effective when started early, before the disease has the opportunity to progress further.

Disease-modifying medications

- Reduce the frequency and severity of clinical attacks (also called relapses or exacerbations). An attack is defined as the worsening of an MS symptom or symptoms, and/or the appearance of new symptoms, which lasts at least 24 hours and is separated from a previous exacerbation by at least one month.
- Reduce the accumulation of lesions (damaged or active disease areas) within the brain and spinal cord as seen on MRI (magnetic resonance imaging).
- Appear to slow down the accumulation of disability.

These medications, which are generally taken on a long-term basis, are the best defense currently available to slow the natural course of MS. Even though the disease-modifying medications don't generally make a person feel better, they can be looked upon as an investment in the future.

Options

There are currently twelve disease-modifying medications approved by the U.S. Food and Drug Administration (FDA) for use in relapsing forms of MS (including secondary-progressive MS for those people who are still experiencing relapses).

Of these, one is also approved specifically for secondary-progressive MS. None of these medications is a cure, and none will prevent recurring symptoms, such as fatigue or numbness. However each of them has a proven record of effectiveness. Unfortunately, no disease-modifying medication has yet been approved to treat primary progressive MS — the type of MS that shows steady progression at onset.

Decisions about taking a disease-modifying medication are best made by carefully considering and weighing factors including individual lifestyle, disease course, known side effects, and the potential risks and benefits of the different therapies. A full discussion with a knowledgeable healthcare professional is the best guide for your decision. Each person's body or disease can respond to these medications in different ways.

The following charts present important information about each of the medications, which are listed in alphabetical order.

Brand (Generic Name) & Frequency/Route of Delivery/Usual Dose

Aubagio® *(teriflunomide)*
Every day; pill taken orally; 7 mg or 14 mg.

Avonex® *(interferon beta-1a)*
Once a week; intramuscular (into the muscle) injection; 30 mcg.

Betaseron® *(interferon beta-1b)*
Every other day; subcutaneous (under the skin) injection; 250 mcg.

Copaxone® *(glatiramer acetate)*
Every day; subcutaneous (under the skin) injection; 20 mg (20,000 mcg) OR Three times a week; subcutaneous (under the skin) injection; 40 mg (40,000 mcg)

Extavia® *(interferon beta-1b)*
Every other day; subcutaneous (under the skin) injection; 250 mcg.

Gilenya® *(fingolimod)*
Every day; capsule taken orally; 0.5 mg.

Lemtrada™ *(alemtuzumab)*
Intravenous infusion on five consecutive days, followed by intravenous infusion on three consecutive days one year later (12 mg)

Novantrone®
(mitoxantrone; as of 2006, available as a generic drug)
Four times a year by IV infusion in a medical facility. Lifetime cumulative dose limit of approximately 8–12 doses over 2–3 years (140 mg/m2).

Plegridy™ *(pegylated interferon beta-1a)*
Every 14 days; subcutaneous (under the skin) injection; 125 mcg.

Rebif® *(interferon beta-1a)*
Three times a week; subcutaneous (under the skin) injection; 44 mcg.

Tecfidera® *(dimethyl fumarate — formerly called BG-12)*
Twice a day; capsule taken orally; 120 mg for one week and 240 mg therafter.

Tysabri® *(natalizumab)*
Every four weeks by IV infusion in a registered infusion facility; 300 mg.

Manufacturer/Distributor & Year of FDA Approval

Aubagio®	Genzyme, a Sanofi company — 2012
Avonex®	Biogen Idec — 1996
Betaseron®	Bayer HealthCare Pharmaceuticals, Inc. — 1993
Copaxone®	Teva Neuroscience — 1996
Extavia®	Novartis Pharmaceuticals Corp. — 2009
Gilenya®	Novartis Pharmaceuticals Corp. — 2010
Lemtrada™	Genzyme, a Sanofi company — 2014
Novantrone®	EMD Serono, Inc./Immunex Corporation — 2000
Plegridy™	Biogen Idec — 2014
Rebif®	EMD Serono, Inc./Pfizer, Inc. — 2002
Tecfidera®	Biogen Idec — 2013
Tysabri®	Biogen Idec — 2006

Indication (FDA-approved Use)

Aubagio®
For the treatment of relapsing forms of MS.

Avonex®
For the treatment of relapsing forms of MS to slow the accumulation of physical disability and reduce the frequency of clinical exacerbations, and for patients who have experienced a first clinical episode and have MRI features consistent with MS.

Betaseron®
For the treatment of relapsing forms of MS to reduce the frequency of clinical exacerbations; and for patients who have experienced a first clinical episode and have MRI features consistent with MS.

Copaxone®
For the treatment of relapsing-remitting MS to reduce the number of clinical exacerbations; and for patients who have experienced a first clinical episode and have MRI features consistent with MS.

Extavia®
For the treatment of relapsing forms of MS to reduce the frequency of clinical exacerbations; and for patients who have experienced a first clinical episode and have MRI features consistent with MS.

Gilenya®
For the treatment of relapsing forms of MS to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.

Lemtrada™
For the treatment of relapsing forms of MS. The FDA indication includes a statement that this medication should generally be reserved for people who have had an inadequate response to two or more disease-modifying therapies.

Novantrone®
For the treatment of worsening relapsing-remitting MS, progressive-relapsing MS or secondary-progressive MS to reduce neurologic disability and/or the frequency of clinical exacerbations.

Plegridy™
For the treatment of relapsing forms of MS.

Rebif®
For the treatment of relapsing forms of MS to reduce the frequency of clinical exacerbations and delay the accumulation of physical disability.

Tecfidera®
For the treatment of relapsing forms of MS.

Tysabri®
To be used as a monotherapy (not in combination with any other disease-modifying medications) for the treatment of relapsing forms of MS. The FDA indication also includes a statement about specific risks associated with this medication that need to be carefully considered. (*See "Tysabri Warnings" page 19.)*

NOTE: Patients taking interferon beta-1a (Avonex or Rebif) or interferon beta-1b (Betaseron or Extavia) medications may develop immunity to the treatment demonstrated by the presence of "neutralizing antibodies" detected in their blood. Some neurologists believe that this is an important factor in managing patients receiving interferon.

Side Effects (always inform your healthcare professional of side effects)

Not every person will experience every one of these side effects. All occurred in at least 2 percent of participants in the clinical trials and were more frequent in the treatment groups than in the groups receiving placebo. Your healthcare provider can give you a better sense of how frequently problems occur with the specific agent he or she recommends for you.

Aubagio®
Hair thinning, diarrhea, flu, nausea, abnormal liver tests and unusual numbness or tingling in the hands or feet (paresthesias). Less common: lowered levels of white blood cells, which can increase the risk of infections; increase in blood pressure; severe liver damage *(See "Aubagio Warnings" on page 10.)*

Avonex®
Flu-like symptoms following injection, which lessen over time for many. *(See "Managing side effects" below.)* Less common: depression, mild anemia, liver abnormalities, allergic reactions, heart problems. *(See "Avonex Warnings" on page 11.)*

Betaseron®
Flu-like symptoms following injection, which lessen over time for many. *(See "Managing side effects" below.)* Injection site reactions. Less common: allergic reactions, depression, liver abnormalities, low white blood cell counts. *(See "Betaseron Warnings" on page 12.)*

Copaxone®
Injection site reactions. Less common: vasodilation (dilation of blood vessels); chest pain; a reaction immediately after injection, which includes anxiety, chest pain, palpitations, shortness of breath, and flushing. This lasts 15-30 minutes, typically passes without treatment, and has no known long-term effects. *(See "Copaxone Warnings" on page 12.)*

Extavia®
Flu-like symptoms following injection, which lessen over time for many. *(See "Managing side effects" below.)* Injection site reactions. Less common: allergic reactions, depression, liver abnormalities, low white blood cell counts. *(See "Extavia Warnings" on page 13.)*

Gilenya®
Headache, flu, diarrhea, back pain, liver enzyme elevations and cough. Less common: slowed heart rate following first dose, infections, swelling in the eye. *(See "Gilenya Warnings" on page 13.)*

Lemtrada™
Rash, headache, fever, nasal congestion, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, hives, itching, thyroid gland disorders, fungal Infection, pain in joints, extremities and back, diarrhea, vomiting, flushing. Infusion reactions (including nausea, hives, itching, insomnia, chills, flushing, fatigue, shortness of breath, changes in the sense of taste, indigestion, dizziness, pain) are also common while the medication is being administered and for 24 hours or more after the infusion is over, *(See "Lemtrada Warnings" on page 14.)*

Novantrone®
Blue-green urine 24 hours after administration; infections, bone marrow suppression (fatigue, bruising, low blood cell counts), nausea, hair thinning, bladder infections, mouth sores. Patients must be monitored for serious liver and heart damage. *(See "Novantrone Warnings" on page 16.)*

Plegridy™
Flu-like symptoms following injection. *(See "Managing side effects" below.)* Injection site reactions. Less common: depression, mild anemia, liver abnormalities, allergic reactions, heart problems. *(See "Plegridy Warnings" on page 16.)*

Rebif®
Flu-like symptoms following injection, which lessen over time for many. *(See "Managing side effects" below.)* Injection site reactions. Less common: liver abnormalities, depression, allergic reactions, and low red or white blood cell counts. *(See "Rebif Warnings" on page 17.)*

Tecfidera®
Flushing (sensation of heat or itching and a blush on the skin), gastrointestinal issues (nausea, diarrhea, abdominal pain), rash, protein in the urine, elevated liver enzymes; reduction in blood lymphocyte (white blood cell) counts. *(See "Tecfidera Warnings" on page 18.)*

Tysabri®
Headache, fatigue, urinary tract infections, depression, respiratory tract infections, joint pain, upset stomach, abdominal discomfort, diarrhea, vaginitis, pain in the arms or legs, rash. Less common: allergic or hypersensitivity reactions within two hours of infusion (dizziness, fever, rash, itching, nausea, flushing, low blood pressure, difficulty breathing, chest pain). *(See "Tysabri Warnings" on page 19.)*

Managing side effects of disease-modifying medications

Not everyone will experience every one of these side effects. Some adverse effects are common, and others are very infrequent but may be serious. Your healthcare provider can give you a better sense of how frequently problems occur with the specific agent he or she recommends for you and guide you on how to manage any side effects that occur. The industry-sponsored websites (page 22) also give you information about the side effects you may experience.

Aubagio® Warnings

The prescribing information for Aubagio (teriflunomide) includes the following boxed warnings:

- Aubagio can cause liver damage. A blood test to detect levels of liver enzymes should be given before starting the medication and then repeated monthly for six months, followed by monitoring for damage to the liver. In the event of significant liver problems, people should stop taking Aubagio immediately. Because Aubagio is known to remain in the blood for as long as two years after a person stops taking it, treatment regimens are available to remove the medication rapidly from the body.
- Aubagio can cause major birth defects for up to two years after the medication is discontinued. A woman should be given a pregnancy test prior to starting the medication and should use effective birth control while taking the medication.

If she becomes pregnant accidentally, she should stop taking Aubagio immediately and undergo treatment to remove the medication rapidly from the body. Men who plan to father a child should stop taking the medication and undergo treatment to remove the medication rapidly from the body before they and their partners try to conceive.

- Aubagio can increase a person's risk of infections. People should have a complete blood count prior to starting treatment and be monitored for infection while on treatment. People should also be tested for latent tuberculosis before starting treatment. A person who tests positive for tuberculosis should not begin taking Aubagio until the treatment for tuberculosis has been successfully completed.
- Aubagio can cause damage to nerves in the peripheral nervous system (peripheral neuropathy); monitoring for symptoms of peripheral neuropathy should continue throughout treatment.
- Aubagio can cause acute kidney failure and elevated potassium in the blood. Renal function should be monitored in anyone who experiences symptoms of renal failure or elevated potassium levels.
- Aubagio can cause elevations in blood pressure; blood pressure should monitored and managed during treatment.

Avonex® Warnings

In response to events reported by patients and clinicians following approval of this medication, the FDA has added the following warnings about Avonex (interferon beta-1a): Individuals with a history of depression, a seizure disorder, or cardiac problems should be closely monitored while on this medication; All patients on this medication should have baseline liver function testing and periodic testing thereafter; Periodic blood testing is recommended to check for a possible reduction in infection-fighting blood cells, red blood cells, and cells that help blood to clots; Rare but significant allergic reactions have been reported to this medication.

Betaseron® Warnings

In response to events reported by patients and clinicians following approval of this medication, the FDA has added the following warning about Betaseron (interferon beta-1b): Individuals with a history of depression or a seizure disorder should be closely monitored while on this medication; This medication should be used with caution in people with depression; Rare but significant allergic reactions have been reported with this medication; Because skin infections or areas of severe skin damage can occur, injection sites should be rotated on a regular basis.

Copaxone® Warnings

The FDA labeling for Copaxone (glatiramer acetate) contains the following warnings: Approximately 16% of people will experience an immediate post-injection reaction that includes at least two of the following: flushing, chest pain, palpitations, anxiety, shortness of breath, constriction of the throat, and transient skin eruptions. These symptoms generally disappear spontaneously after about 15 minutes and have no long-term effects.

This post-injection reaction generally occurs after the first few months of treatment and may occur more than once in a given individual. Transient chest pain — without any long-term effects — may also occur one or more times, either as part of the post-injection reaction or separately. Permanent depressions under the skin at injection sites can occur because of destruction of the fatty tissue. In addition, areas of severe skin damage can occur. For these reasons, careful rotation of injection sites is recommended so that no single area is injected more than one time per week.

Extavia® Warnings

Because Extavia (interferon beta-1b) is identical to Betaseron® (interferon beta-1b), the FDA labeling includes the same warnings.

Gilenya® Warnings

- Because Gilenya can cause a person's heart rate to temporarily slow after the first dose, all patients should be given an electrocardiogram (ECG) prior to the first dose, monitored for six hours after the first dose with hourly pulse and blood pressure measurement, and then given a repeat ECG. If cardiac symptoms persist after the six-hour observation period, observation and continuous ECG monitoring should be maintained until the problems are resolved. In addition, any person with a history of cardiac problems should be carefully evaluated before starting treatment with Gilenya. Anyone who has experienced a heart attack, unstable angina, a stroke or stroke warning, or certain types of heart failure within the past six months should not begin treatment with Gilenya. People who take a medication that affects their heart rhythm should not take Gilenya.
- Blood pressure should be monitored during treatment with Gilenya.
- Because this medication reduces the number of white blood cells, a blood test to measure white blood cell count is recommended prior to starting treatment.
- If a person has not had chicken pox (varicella), his or her doctor may recommend the varicella vaccine prior to starting this medication.
- Gilenya can affect respiratory function. Anyone who experiences changes in their breathing should be evaluated.
- A vision test is recommended prior to starting treatment and about 3 months later to look for evidence of macular swelling in the eye.
- Because Gilenya can cause liver problems, a liver function test is recommended prior to starting treatment.

Lemtrada™ Warnings

The FDA labeling for Lemtrada includes a warning about the potential for serious, sometimes fatal, autoimmune conditions such as immune thrombocytopenia (ITP, a rare bleeding condition) and anti-glomerular basement membrane disease (which impacts the kidneys). The prescribing information also warns about serious and life-threatening infusion reactions (while the medication is being given and for 24 hours after each infusion), increased risk of malignancies (thyroid cancer, melanoma, and blood cancers). Because of these risks, the FDA recommends the following screening and monitoring strategies:

- Prior to treatment, it should be determined whether the person has adequate immunity to the varicella zoster virus. If the person does not, the varicella vaccine should be administered 6 weeks prior to starting the medication.
- Thyroid function tests should be obtained before treatment and every 3 months until 48 months after the last infusion.
- Full blood count looking at different types of white and red blood cells should be obtained prior to treatment and monthly thereafter until 48 months after the last infusion.
- Blood tests to assess kidney function levels should be obtained prior to treatment and monthly thereafter until 48 weeks after the last infusion.
- Urinalysis with urine cell counts should be obtained prior to treatment and monthly thereafter until 48 months after the last Infusion.
- A skin exam should be done at the start of treatment and yearly thereafter to monitor for melanoma (a type of skin cancer).
- A person with an active infection should not start treatment until the infection is controlled.
- People should not have a live virus vaccine after a course of Lemtrada.

Because of the risks associated with Lemtrada, this treatment is only available from certified prescribers and pharmacies, and people taking the medication, as well as the healthcare facility administering the medication, must be enrolled in a Risk Evaluation and Mitigation Strategy (REMS) program to ensure that all the required screening and monitoring requirements are followed in a timely way.

Novantrone® Warnings

Novantrone (mitoxantrone) is a chemotherapeutic treatment originally developed to treat certain forms of cancer. The total lifetime dose is limited in order to avoid possible heart damage. People taking Novantrone should have tests of their heart function before each dose and periodically after treatment has ended. It cannot be used in people with pre-existing heart problems, liver disease, and certain blood disorders. In addition to cardiac toxicity, acute myelogenous leukemia (AML), a type of cancer, has been reported in MS patients and cancer patients treated with Novantrone. AML can be fatal. For these reasons, Novantrone is seldom prescribed any more.

Plegridy™ Warnings

The FDA labeling for Plegridy contains the following warnings:

- Because this medication can cause liver damage, monitoring for signs and symptoms of liver injury is recommended.
- Plegridy may increase the risk of depression and suicide, particularly in individuals with a prior history of depression. Patients taking this medication should be monitored for mood changes and should report any changes to their healthcare provider.
- Seizures can occur in people taking an interferon beta medication. Plegridy should be used with caution in anyone with a seizure disorder.
- Because injection site reactions can occur with Plegridy, proper injection techniques and the rotation of injection sites are important.

- Patients with significant pre-existing cardiac disease should be monitored closely while on Plegridy since congestive heart failure can occur.
- Periodic blood testing is recommended to check for a possible reduction in infection-fighting blood cells, red blood cells, and cells that help blood to clots.
- Rare but severe allergic reactions have occurred as a rare complication of treatment with an interferon beta medication.

Rebif® Warnings

In response to events reported by patients and clinicians following approval of this medication, the FDA has added the following warnings about Rebif (interferon beta-1a):

- Individuals with a history of depression or a seizure disorder should be closely monitored while on this medication.
- All patients on this medication should have baseline liver function testing and periodic testing thereafter.
- Periodic blood testing is recommended to check for a possible reduction in infection-fighting blood cells, red blood cells, and cells that help blood to clots.
- Rare but significant allergic reactions have been reported to this medication.

Tecfidera® Warnings

The FDA labeling for Tecfidera contains the following warnings:

- Tecfidera (dimethyl fumarate) can cause severe allergic reactions, including anaphylaxis (a reaction that occurs very quickly and may include itchy rash, difficulty breathing and swelling of the throat, and angioedema (a swelling under the skin that typically occurs in the throat and tongue). An allergic reaction can occur after the first dose or at any time during treatment. A person who experiences any of these symptoms should stop the mediation and seek medical care immediately.
- One person taking Tecfidera for four years while enrolled in a clinical trial developed progressive multifocal leukoencephalophy (PML -- see p. 20) after the trial ended, and died. PML typically occurs only in people whose ability to fight infection has been severely reduced. Among people being treated for MS, PML had previously occurred only in those taking Tysabri. This person had very low numbers of white blood cells called lymphocytes (lymphopenia) but the role of the lymphopenia in this case of PML is not known. The person had no other risk factors for PML. Symptoms of PML progress over days to weeks and include progressive weakness on one side of the body, clumsiness, vision changes and changes in thinking, memory and orientation that lead to confusion and personality changes. Anyone experiencing changes of this kind while taking Tecfidera should report them immediately to his or her healthcare provider.
- Tecfidera may reduce blood lymphocyte counts significantly. During the clinical trials, the average lymphocyte counts dropped approximately 30% during the first year and then remained stable.

Four weeks after stopping the medication, lymphocyte counts increased but did not return to the baseline level.

- Prior to starting this medication, a complete blood count (CBC), including lymphocyte count, should be done, followed by another CBC after six months of treatment, and every 6-12 months thereafter, or more often If the healthcare provider feels it is necessary.
- An interruption of treatment may be considered if a person's lymphocyte count drops very low and remains low for more than six months.
- Healthcare providers should consider withholding treatment for any person with a serious infection until the infection has resolved.

Tysabri® Warnings

Tysabri (natalizumab) is a laboratory-produced monoclonal antibody that is given by intravenous (IV) infusion every four weeks. Tysabri cannot be infused at home, so your doctor will help you find an infusion center.

When talking with your healthcare professional about starting treatment with Tysabri, it is important to consider the following information: Individuals taking Tysabri are at increased risk for a rare, often fatal brain disease called PML (progressive multifocal leukoencephalopathy), which is caused by the common JC virus. They are also at risk for liver damage and certain types of herpes infections of the central nervous system.

PML

There are no interventions that are known to cure PML once it occurs, but a course of plasma exchange to remove Tysabri® from the bloodstream as quickly as possible may provide benefit.

For people taking Tysabri, three factors increase the risk of PML: longer treatment duration (particularly beyond two years), previous treatment with an immunosuppressant medication and testing positive for antibodies to the JC virus (which indicates that a person has previously been exposed to the JC virus). The availability of a laboratory test to test JC-antibody status has made it easier for people with MS and their physicians to weigh the risks and benefits of this therapy.

The medication label suggests that the risks and benefits of starting or continuing Tysabri should be carefully considered in patients who test positive for antibodies to the JC virus and have one or both of the other risk factors. Those found to be antibody positive, have used Tysabri for less than two years, and have no prior use of immune suppressing drugs are estimated to have a risk of PML of less than 1/1000; those with all three known risk factors have an estimated risk of PML of 13/1000.In individuals who are antibody negative, have no prior history of immunosuppression, and take Tysabri for less than two years, the risk of PML is approximately 1/50,000.

A person who tests negative for anti-JCV antibodies is still at risk for the development of PML for two very important reasons. First, she or he can be infected by the JC virus at any time without knowing it. Second, the laboratory test to

detect antibodies to the JC virus will produce a false negative result about three percent of the time. Therefore, testing should be done prior to starting treatment with Tysabri, and repeated every six months while a person is on treatment. For the purposes of risk evaluation, a person who tests positive for JC virus antibodies at any point in time is considered to be antibody-positive even if he or she tests negative on a later test. Careful monitoring for PML should continue for six months after treatment has ended.

Because of the risk of PML, Tysabri® is only available under a restricted distribution program, referred to as the TOUCH® program, which was created to monitor patients for PML and other adverse effects. Prescribing physicians and patients must enroll in this mandatory registry program. Infusion centers must also be enrolled in the TOUCH® program. Patients using Tysabri should promptly report any continuously worsening symptoms to their prescriber.

Liver Damage

Based on post-marketing experience with Tysabri, the FDA has added an additional warning to the product's labeling information. Tysabri has been found to increase the risk of liver damage, even after the first dose. Liver failure requiring a liver transplant has also occurred. Any person experiencing symptoms of liver injury, including yellowing of the skin and eyes (jaundice) unusual darkening of the urine, nausea, feeling tired or weak, and vomiting, should contact his or her physician immediately. Blood tests can be done to check for liver damage.

Serious Herpes Infections

Infections of the brain and spinal cord (encephalitis) and of surrounding tissues (meningitis), caused by herpes viruses, can also occur in people taking Tysabri. It is critical to report any of the following to your physician — sudden fever, severe headache, vision change (especially light sensitivity), stiff neck, behavior change or change in cognition — so that treatment with an antiviral medication can be started.

Tysabri is **not** recommended for use by any person whose immune system is weakened by disease or by the use of medications that alter the immune system, including other disease-modifying therapies.

Warnings about IV infusions

All medications delivered by IV infusion pose risks of bruising, vein damage, blood clots and more. Infusions must be managed by a well-trained medical professional who is qualified to administer them.

Industry-Sponsored Sites for Patient Information and/or Financial Assistance

Aubagio®
MS One to One®
MSOnetoOne.com
855-676-6326

Avonex®
MS ActiveSource®
avonex.com | *msactivesource.com*
800-456-2255

Betaseron®
BETAPLUS®
betaseron.com
800-788-1467

Copaxone®
Shared Solutions®
copaxone.com/AboutSharedSolutions.aspx
800-887-8100

Extavia®
extavia.com
Extavia *Go Program*
866-398-2842
Patient Assistance NOW
patientassistancenow.com
800-245-5356

Gilenya®
gilenya.com
Gilenya *Go Program*
800-445-3692
Patient Assistance NOW
patientassistancenow.com
800-245-5356

Lemtrada™
MS One to One®
MSOnetoOne.com
855-676-6326

Novantrone®
No patient support program at this time

Plegridy™
MS ActiveSource®
plegridy.com | *msactivesource.com*
800-456-2255

Rebif®
MS LifeLines™
rebif.com | *mslifelines.com*
877-447-3243

Tecfidera®
MS ActiveSource®
tecfidera.com | *msactivesource.com*
800-456-2255

Tysabri®
MS ActiveSource®
tysabri.com | *msactivesource.com*
800-456-2255

Benefits of the Disease-Modifying Medications

Reducing the frequency of attacks and new lesions as seen on MRI

All of these medications have been shown to reduce the frequency of MS relapses and the development of new lesions. In individual clinical trials comparing a drug versus an inactive

placebo treatment, MS attacks were reduced by 28–68 percent by different agents. In the clinical trials, most people were also found to have fewer, smaller, or no new lesions developing within their central nervous system as visible in MRI scans. Some of these medications have also been shown to delay the progression of disability.

Preventing permanent damage

Permanent damage to nerve fibers (called axons) occurs early in MS in association with the destruction of myelin. Overall brain shrinkage (or atrophy), can occur early in the disease, and damage can be ongoing even when the person has no symptoms of an attack and feels well. Therefore, MS specialists advise the early use of a medication that effectively limits lesion formation and brain atrophy, or shrinkage. In the opinion of the National MS Society's Medical Advisory Committee, limiting lesions may be a key to reducing future permanent disability for many people with MS.

None of these medications is recommended for women who are pregnant or plan to become pregnant. Physicians should be consulted. Most women will be advised to avoid using these medications during pregnancy.

The bottom line

Many factors will influence the decision that you and your physician make about your choice of medication. One of them will be lifestyle issues that could affect your ability to stay with a treatment over time. Another factor is your response to the therapy, which should be carefully tracked. If your MS is not responding, you and your physician should discuss your options.

Paying for a Disease-Modifying Medication: Some Help is Available

Disease-modifying medications are costly. The actual cost to an individual or an insurance company will vary depending on the source. Because cost information is subject to frequent change, we recommend that you contact your healthcare plan and/or your pharmacy for cost information.

Some private insurance plans do not cover prescription medications, although they may cover procedures such as IV infusions in a medical facility. Plans that do cover prescription medications often have a list of the specific drugs covered by the plan (known as a formulary). It is possible that some disease-modifying medications are covered by a plan and some are not. In addition, many formularies now distinguish between "preferred" and "non-preferred" drugs, or put drugs on different tiers. The co-insurance amounts you may have to pay as a result can vary significantly.

Because Novantrone®, Tysabri® and Lemtrada™ must be infused in a medical facility, they are covered under Medicare Part B. If Avonex® is administered in a physician's office or clinic, it will be covered by Medicare Part B under most circumstances. For more detailed information, contact MS ActiveSource® (800-456-2255).

Medicare Part D covers prescription drugs through private plans approved by Medicare. For more information on Medicare prescription drug coverage, go to: **nationalMSsociety.org/medicare**, or call 1-800-344-4867.

Medicaid includes prescription drug coverage. However, the list of specific medications covered may vary from state to state. Call your state Medicaid office for more information.

Each of the pharmaceutical companies offers a program designed to help people apply for and use all the state and federal programs for which they are eligible.

They also help some people who are uninsured or under-insured through patient assistance programs. The companies invite physicians and people with MS who might be deterred by the cost from considering a disease-modifier to call the toll-free numbers listed in the chart entitled "Industry-Sponsored Sites" *(page 22)*. Ask for information on available assistance.

For additional information on specific industry assistance, visit: **nationalMSsociety.org/AssistancePrograms**.

Help with the Cost of Medications for Symptom Management

In addition to the disease-modifying medications discussed above, there are many other medications, treatments, and strategies to help manage specific MS symptoms such as bowel and bladder function, spasticity and pain. Symptom management medications make important contributions to keeping people with MS well and active.

"Finding Lower-Priced Prescription Drugs" is a useful resource focused on making medications more affordable. Visit our website at **nationalMSsociety.org/insurance** for more information.

For detailed information on patient assistance programs from drug manufacturers, visit **needymeds.org**.

A Recommended Resource

The Multiple Sclerosis Emerging Therapies Collaborative — which includes the MS Coalition, the American Academy of Neurology, the VA Multiple Sclerosis Centers of Excellence East and West, and ACTRIMS — provides timely, evidence-based information about emerging therapies for people affected by multiple sclerosis and healthcare professionals. The Collaborative's goal is to

promote optimal, personalized treatment by facilitating effective doctor-patient communication and collaborative decision-making. Visit their Website at **ms-coalition.org/EmergingTherapies**.

The National Multiple Sclerosis Society ("Society") is proud to be a source of information on multiple sclerosis related topics. The information provided is based on professional advice, published experience, and expert opinion, but does not constitute medical or legal advice. For specific medical advice, consult a qualified physician. For specific legal advice, consult a qualified attorney.

The Society does not endorse products, services or manufacturers. Such names appear here solely because they are considered helpful information. The Society assumes no liability for the recipient's use of any product or service mentioned. The Society does not independently verify whether the information provided by each service provider is accurate. The Society undertakes no responsibility to verify whether the service provider is appropriately licensed and certified and has applicable insurance coverage.

Early and ongoing treatment with an FDA-approved therapy can make a difference for people with multiple sclerosis. Learn about your options by talking to your healthcare professional and contacting the National MS Society at **nationalMSsociety.org** or 1-800-344-4867 (1-800-FIGHT-MS).

The Society publishes many other resources about various aspects of MS. Visit **nationalMSsociety.org/brochures** or call 1-800-344-4867.

The National MS Society is a collective of passionate individuals who want to do something about MS now — to move together toward a world free of multiple sclerosis.

We help each person address the challenges of living with MS through our 50-state network of chapters. The Society helps people affected by MS by funding cutting-edge research, driving change through advocacy, facilitating professional education, and providing programs and services that help people with MS and their families move their lives forward.

National
Multiple Sclerosis
Society

nationalMSsociety.org

For Information:
1 800 FIGHT MS (1 800 344 4867)

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