DISEASE-MODIFYING THERAPIES FOR MS



Updated April 2021. Please visit **nationalMSsociety.org/DMT** for the most current version of this publication.

Although a cure for MS has not yet been discovered, a number of medications (also called disease modifying therapies, or DMTs) have been approved to treat MS. **Permanent** damage to the central nervous system (or CNS, which is made up of the brain, spinal cord and optic nerves) can occur early in the disease, even when a person has no symptoms and feels well. Early and ongoing treatment with DMTs may help prevent permanent damage in the CNS. Research has demonstrated the DMTs for relapsing forms of MS reduce the frequency and severity of MS relapses, reduce the development of new areas of damage in the CNS and slow the accumulation of disability. Disease modifying therapies don't generally improve everyday symptoms. Many symptoms of MS can be managed using other types of medications and non-medication strategies. Combining DMT use, symptom management and a **healthy lifestyle** is the optimal strategy for managing MS.

Working with your healthcare provider to find the best choice for you

The decision to take a DMT should be a shared decision made jointly between you and your healthcare provider. Each person's body or disease can respond to DMTs differently, and the DMT that is the best option for one person may not be the best for another person. In addition, a DMT that adequately controls your disease today may not do so in the future and you may need to change to a different DMT. Also make sure your provider knows what other health conditions and medications (including vitamins and supplements) you take as that can affect which DMTs are safe for you.

Help with DMT costs

Learn more about patient assistance programs to help with the cost of each DMT at nationalMSsociety.org/assistanceprograms. For additional information, connect to an MS Navigator at 1-800-344-4867 or **contactus@nmss.org**.

Understanding US Food and Drug Administration (FDA) warnings

The chart below summarizes the side effects, warnings and precautions listed for each DMT in the FDA required prescribing information. In some instances, a warning is printed in a black box in the prescribing information to call attention to serious or life-threatening risks. All black box warnings are in **bold** font in the column outlining the 'Side effects and warnings' in the chart.

Each DMT can cause a serious allergic reaction and some make it unsafe for you to receive certain vaccines while you're taking them. Prior to starting any DMT, talk with your healthcare provider about any vaccines you should get or have recently received. Each DMT requires some safety monitoring. Talk with your healthcare provider about the monitoring that is required for the DMT you are taking and be consistent with it.

None of the DMTs are approved by the FDA for women who are pregnant or plan to become pregnant, or who are breastfeeding. It is important for women to discuss their plans for pregnancy with their healthcare provider so that they can decide together the best and safest treatment plan.

Important information

Injectable treatments				
Treatment (chemical name)	Dose/Route of Administration	Side effects and warnings		
Manufacturer FDA indications	Pregnancy, family planning & breastfeeding	(black box warnings are noted in bold)		
Avonex® (interferon beta-1a) Biogen Approval: 1996 US, for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.	30 mcg intramuscular (into a large muscle) injection once weekly Pregnancy: Data do not suggest a clear relationship between use and major congenital malformations, but may cause fetal harm based on animal data	Most common side effects: headache, flu-like symptoms (chills, fever, muscle pain, fatigue weakness), injection site pain and inflammation Possible serious side effects: • Depression, suicidal thoughts, hallucinations or other behavioral health problems • Liver problems, or worsening of liver problems including liver failure and death • Heart problems, including heart failure • Blood problems, including low red and white blood cell and platelet counts • Injury to small blood vessels, red blood cells and platelets (thrombotic microangiopathy), sometimes leading to death • Autoimmune diseases—easy bleeding or bruising, thyroid gland problems and autoimmune hepatitis Read the medication guide for a comprehensive overview of side effects and risks associated with this medication		

Injectable treatments

Treatment (chemical name) Manufacturer FDA indications	Dose/Route of Administration Pregnancy, family planning & breastfeeding	Side effects and warnings (black box warnings are noted in bold)		
Betaseron® (interferon beta-1b) Bayer Healthcare Pharmaceuticals Inc. Approval for RRMS: 1993 US; 1995 CAN Approval for SPMS: 1995 CAN for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.	0.25 mg subcutaneous (under the skin) injection every other day Pregnancy: May cause fetal harm based on animal data	Most common side effects: flu-like symptoms (chills, fever, muscle pain, fatigue, weakness) following injection, headache, injection site reactions (swelling redness, pain), injection site skin breakdown, low white blood cell count, insomnia, abdominal pain, increased liver enzymes Possible serious side effects: Liver problems including liver failure Depression or suicidal thoughts Heart problems or worsening heart problems Injury to small blood vessels, red blood cells and platelets (thrombotic microangiopathy), sometimes leading to death Lupus erythematosus, an autoimmune disease Read the medication guide for a comprehensive overview of side effects and risks associated with this medication.		
Copaxone® (glatiramer acetate) Teva Neuroscience Approval: 1996 US; 1997 CAN Therapeutic equivalent to Copaxone: Glatiramer Acetate Mylan Pharmaceuticals Approval: 2017 US, for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.	20 mg subcutaneous (under the skin) injection every day, or 40 mg subcutaneous injection three times per week Pregnancy: Available human data are not sufficient to support conclusions about drug-associated risk for major birth defects and miscarriage	Most common side effects: injection site reactions (redness, pain, swelling), flushing, shortness of breath, rash, chest pain Possible serious side effects: • Damage to the fatty tissue under the skin (lipoatrophy) and, rarely, death of skin tissue (necrosis) • Liver problems Read the Copaxone medication guide for a comprehensive overview of side effects and risks associated with this medication. Read the Mylan glatiramer acetate medication guide for 20 mg and the medication guide for 40 mg.		

Injectable treatments				
Treatment (chemical name) Manufacturer FDA indications	Dose/Route of Administration Pregnancy, family planning & breastfeeding	Side effects and warnings (black box warnings are noted in bold)		
Extavia® (interferon beta-1b) Novartis Pharmaceuticals Approval: 2009 US; 2009 CAN, for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.	0.25 mg subcutaneous (under the skin) injection every other day Pregnancy: May cause fetal harm based on animal data	Most common side effects: flu-like symptoms (chills, fever, muscle pain, fatigue, weakness) following injection, headache, injection site reactions (swelling redness, pain), injection site skin breakdown, low white blood cell count, insomnia, abdominal pain, increased liver enzymes Possible serious side effects: Liver problems including liver failure Depression or suicidal thoughts Injury to small blood vessels, red blood cells and platelets (thrombotic microangiopathy), sometimes leading to death Read the medication guide for a comprehensive overview of side effects and risks associated with this medication.		
Glatopa® (glatiramer acetate, generic equivalent of Copaxone) Sandoz – a Novartis company Approval: 2015 US, for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.	20 mg subcutaneous (under the skin) injection every day, or 40 mg subcutaneous injection three times per week Pregnancy: Available human data are not sufficient to support conclusions about drug-associated risk for major birth defects and miscarriage	Most common side effects: Injection site reactions (redness, pain, swelling), flushing, shortness of breath, rash, chest pain Possible serious side effects: • Damage to the fatty tissue under the skin (lipoatrophy) and, rarely, death of skin tissue (necrosis) • Liver problems Read the medication guide for a comprehensive overview of side effects and risks associated with this medication.		

Injectable treatments

Treatment (chemical name)

Manufacturer

FDA indications

Dose/Route of Administration

Pregnancy, family planning & breastfeeding

Side effects and warnings (black box warnings are noted in bold)

Kesimpta[®]

(ofatumumab)

Novartis

Approval: 2020 US, for the treatment of relapsing forms of multiple sclerosis. which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.

20 mg subcutaneous (under the skin) injection at week 0, 1 and 2 followed by 20 mg once monthly starting at week 4

Pregnancy: May cause fetal harm based on animal data

Most common side effects:

Upper respiratory tract infection, headache, injection-related and injection-site reactions

Possible serious side effects:

- Hepatitis B virus (HBV) reactivation
- Infections
- A decrease in some types of antibodies (immunoglobulins)

Read the **medication guide** for a comprehensive overview of side effects and risks associated with this medication.

Plegridy®

(pegylated interferonbeta-1a)

Biogen

Approval: 2014 US, for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease. in adults.

63 mcg subcutaneous (under the skin) or intramuscular (into a large muscle) injection on day 1, 94 mcg on day 15, and 125 mcg on day 29 and every 14 days thereafter

Pregnancy: Data do not suggest a clear relationship between use and major congenital malformations, but may cause fetal harm based on animal data.

Most common side effects:

Flu-like symptoms (chills, fever, muscle pain, fatigue, weakness, headache, itching), injection site reactions (swelling, redness, pain)

Possible serious side effects:

- Liver problems or worsening of liver problems, including liver failure and death
- Depression or suicidal thoughts
- Seizures
- Injection site reactions, including severe skin damage (necrosis)
- Heart problems, including congestive heart failure
- Blood problems and changes in your blood tests
- Injury to small blood vessels, red blood cells and platelets (thrombotic microangiopathy), sometimes leading to death
- Autoimmune diseases—easy bleeding or bruising, thyroid gland problems and autoimmune hepatitis

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Dose/Route of Treatment Administration (chemical name) Side effects and warnings Manufacturer Pregnancy, (black box warnings are noted in bold) family planning FDA indications & breastfeeding Rebif® 22 mcg or 44 mcg Most common side effects: Flu-like symptoms (chills, fever, muscle pain, fatigue, subcutaneous (under the (interferon beta-1a) skin) injection three times weakness, headache), injection site reactions (redness, per week pain, swelling) EMD Serono, Inc / Pfizer, Inc Pregnancy: Data do Possible serious side effects: Approval: 1998 US; not suggest a clear • Behavioral health problems including depression and relationship between 2002 CAN, for the suicidal thoughts treatment of relapsing use and major congenital • Liver problems or worsening of liver problems including forms of multiple malformations, but may liver failure sclerosis, which cause fetal harm based on • Injection site problems, including skin damage include clinically animal data. (necrosis) isolated syndrome, Low blood cell counts relapsing-remitting • Injury to small blood vessels, red blood cells and disease (RRMS) and platelets (thrombotic microangiopathy), sometimes active secondary leading to death progressive disease, Seizures in adults. Read the **medication guide** for a comprehensive overview of side effects and risks associated with this medication.

Treatment (chemical name)

Manufacturer

FDA indications

Dose/Route of Administration

Pregnancy, family planning & breastfeeding

Side effects and warnings (black box warnings are noted in bold)

Aubagio®

(teriflunomide)

Sanofi Genzyme

Approval: 2012 US; 2013 CAN, for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.

7 mg or 14 mg pill by mouth once daily

Pregnancy:

Contraindicated for use in pregnant women and in females of reproductive potential who are not using effective contraception because of the potential for fetal harm. Females should not take if they are pregnant or plan to become pregnant. Males should not take if their partner plans to becomes pregnant. Effective birth control should be used by males and females if either partner is taking Aubagio or still has Aubagio in their blood. Aubagio can remain in the blood for up to 2 years after stopping taking it. A healthcare provider can prescribe medication to lower Aubagio blood levels

more quickly.

Most common side effects:

Headache, hair thinning, diarrhea, nausea, abnormal liver tests

Possible serious side effects:

- Severe liver problems including death
- Decrease in white blood cell count and more frequent infections
- Numbness and tingling in the hands or feet that is different from MS symptoms
- High blood pressure
- Serious skin reactions that may lead to death

Oral treatments Dose/Route of **Treatment** Administration (chemical name) Side effects and warnings Manufacturer Pregnancy, (black box warnings are noted in bold) family planning **FDA** indications & breastfeeding Bafiertam™ 95 mg capsule by mouth Most common side effects: twice daily for 7 days Flushing, abdominal pain, diarrhea and nausea (monomethyl fumarate) and 190 mg twice a day **Banner Life Sciences** thereafter Possible serious side effects: • Herpes zoster (shingles) and other serious infections Approval: 2013 US, Pregnancy: May cause • Decreases in white blood count for the treatment of fetal harm based on • Serious liver problems that may lead to death relapsing forms of animal data multiple sclerosis. Read the **medication guide** for a comprehensive which include clinically overview of side effects and risks associated with isolated syndrome, this medication. relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults. Gilenya® 0.5 mg capsule by mouth Most common side effects: once daily for adults and (fingolimod) children weighing greater **Novartis Pharmaceuticals** than 40 kg or 0.25 mg once daily by mouth for Possible serious side effects: children weighing less Approval: 2010 US; 2011 CAN, for the than or equal to 40 kg treatment of relapsing forms of multiple Pregnancy: May cause fetal harm based on sclerosis, which with Gilenva include clinically animal data. Females isolated syndrome, who can become relapsing-remitting pregnant should use severe disability disease (RRMS) and effective birth control active secondary during treatment and for progressive disease, 2 months after stopping

in patients 10 years and older.

Headache, flu, diarrhea, back pain, abnormal liver tests, sinusitis, abdominal pain, pain in extremities, cough

- Infections that may cause death. Do not receive any live vaccines during or for 2 months after stopping treatment. Children need to have completed their vaccination schedule before starting treatment
- Progressive multifocal leukoencephalopathy (PML), a rare brain infection that usually leads to death or
- A vision problem called macular edema that cause some of the same symptoms as an MS vision attack (optic neuritis). Having diabetes or having had inflammation of the eve (uveitis) may increase this risk
- Swelling and narrowing of the blood vessels in your brain called Posterior Reversible Encephalopathy Syndrome (PRES) has happened rarely in adults may lead to stroke if left untreated
- Shortness of breath
- Severe worsening of multiple sclerosis symptoms after stopping treatment
- · Increased blood pressure
- Types of skin cancer called basal cell carcinoma and melanoma

Treatment (chemical name)

Manufacturer

FDA indications

Dose/Route of Administration

Pregnancy, family planning & breastfeeding

Side effects and warnings (black box warnings are noted in bold)

Mavenclad®

(cladribine)

EMD Serono, Inc.

Approval: 2019 US; 2017 CAN for the treatment of relapsing forms of MS, to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use is generally recommended for those who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS.

Tablet given by mouth in two treatment courses, once per year for two vears. Each treatment course has two cycles. which are 4-5 days long and about one month apart. The exact dose will depend on your weight

Pregnancy:

Contraindicated for use in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the risk of fetal harm

It is not known if Mavenclad passes into your breast milk. Do not breastfeed on the days, on which you take Mavenclad and for 10 days after the last dose

Most common side effects:

Respiratory infection, headache, low white blood cell count

Possible serious side effects:

- Increased risk of cancer (malignancy); do not take if you have cancer
- Serious infections such as TB, hepatitis B or C, and shingles (herpes zoster). Fatal cases of TB and hepatitis happened during clinical studies
- Liver problems
- Complications with blood transfusions

Treatment (chemical name)

Manufacturer

FDA indications

Mayzent® (siponimod)

Novartis Pharmaceuticals

Approval: 2019 US, for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.

Dose/Route of Administration

Pregnancy, family planning & breastfeeding

Increases each day over

4-5 days to the ongoing (maintenance) dose of a 1 mg or 2 mg pill by mouth once daily. Your healthcare provider will do a blood test to determine whether you will take the 1 mg or

2 mg maintenance dose and give you specific instructions for increasing the dose each day to reach the maintenance dose.

Pregnancy: May cause fetal harm based on animal data. Tell your healthcare provider right away if you become pregnant while taking Mayzent or if you become pregnant within 10 days after stopping Mayzent. Females taking Mayzent should use effective birth control during treatment and for 10 days after stopping Mayzent.

Most common side effects: Headache, high blood pressure, abnormal liver tests

Possible serious side effects:

- Infections that may cause death
- A vision problem called macular edema that cause some of the same symptoms as an MS vision attack (optic neuritis). Having diabetes or having had inflammation of the eye (uveitis) may increase this risk

Side effects and warnings

(black box warnings are noted in bold)

- Slow heart rate (bradycardia or bradyarrhythmia), especially after the first dose
- New or worsening shortness of breath, including during sleep
- Types of skin cancer called basal cell carcinoma, melanoma and squamous cell carcinoma

Treatment (chemical name)

Manufacturer

FDA indications

Dose/Route of Administration

Pregnancy, family planning & breastfeeding

Side effects and warnings (black box warnings are noted in bold)

Ponvory™ (ponesimod)

Janssen Pharmaceuticals, Inc.

Approval: 2021 US; for the treatment of relapsing forms of multiple sclerosis, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, in adults.

2mg pill by mouth on day one, increased incrementally to a maintenance dose of 20mg on day 15 taken once daily thereafter. Your healthcare provider will give you specific instructions for increasing the dose each day to reach the maintenance dose.

Pregnancy: May cause fetal harm based on animal data. Women of childbearing potential should use effective contraception to avoid pregnancy during and for 1 week after stopping treatment.

Most common side effects:

Upper respiratory tract infection, high blood pressure, abnormal liver tests

Possible serious side effects:

- Infections that may cause death
- Slow heart rate (bradycardia or bradyarrhythmia), especially after the first dose
- New or worsening shortness of breath, including during sleep
- Types of skin cancer called basal cell carcinoma, melanoma and squamous cell carcinoma
- A vision problem called macular edema. Having diabetes or having had inflammation of the eye (uveitis) may increase this risk
- Serious side effects when used with some medications

Oral treatments				
Treatment (chemical name) Manufacturer FDA indications	Dose/Route of Administration Pregnancy, family planning & breastfeeding	Side effects and warnings (black box warnings are noted in bold)		
Tecfidera®	120 mg capsule by	Most common side effects:		
(dimethyl fumarate)	mouth twice daily for one week, followed by	Flushing (sensation of heat or itching and a blush on the skin), gastrointestinal issues (nausea, diarrhea,		
Biogen	240 mg capsule twice daily thereafter	abdominal pain)		
Approval: 2013 US;		Possible serious side effects:		
2013 CAN for the	Drognancy: May cauco	Progressive multifocal leukoencenhalonathy (PMI)		

Pregnancy: May cause fetal harm based on animal data

- Progressive multifocal leukoencephalopathy (PML), a rare brain infection that usually leads to death or severe disability
- Herpes zoster (shingles) and other infections
- Decreases in white blood cell counts
- Liver problems

Dose/Route of Treatment Administration (chemical name) Side effects and warnings **Manufacturer** Pregnancy, (black box warnings are noted in bold) family planning FDA indications & breastfeeding **Vumerity®** 231 mg capsule by mouth Most common side effects: Flushing (redness, itching, rash) and stomach problems twice daily for one week, (diroximel fumarate) followed by two 231 mg (nausea, vomiting, diarrhea, stomach pain, indigestion) capsules taken twice Biogen daily thereafter Possible serious side effects: Approval: 2013 US, • Progressive multifocal leukoencephalopathy (PML), for the treatment of Pregnancy: May cause a rare brain infection that usually leads to death or fetal harm based on relapsing forms of severe disability multiple sclerosis. animal data • Decreases in white blood cell count which include clinically Liver problems isolated syndrome, • Herpes zoster (shingles) and other serious infections relapsing-remitting disease (RRMS) and Read the **medication guide** for a comprehensive active secondary overview of side effects and risks associated with progressive disease. this medication. in adults. Zeposia® 0.23 mg capsule by mouth Most common side effects: (ozanimod) once daily for days 1-4, Upper respiratory tract infections, elevated liver followed by 0.46 mg once enzymes, low blood pressure when you stand up Bristol Myers Squibb daily for days 5-7, then (orthostatic hypotension), painful and frequent urination increased to 0.92 mg (signs of urinary tract infection), back pain and high once daily on day 8 blood pressure Approval: 2020 US, for the treatment of and thereafter. relapsing forms of Possible serious side effects: • Slow heart rate (bradyarrhythmia) when starting multiple sclerosis. Pregnancy: May cause fetal harm based on which include clinically isolated syndrome, animal data. Females • Serious infections that can be life-threatening and relapsing-remitting who can become cause death disease (RRMS) and pregnant should use • Breathing problems active secondary effective birth control • A vision problem called macular edema that cause some progressive disease, of the same symptoms as an MS vision attack (optic in adults. neuritis). Having diabetes or having had inflammation of the eye (uveitis) may increase this risk • Interaction with some medications Read the **medication guide** for a comprehensive overview of side effects and risks associated with this medication.

Intravenous infusion treatments

Treatment (chemical name)

Manufacturer

FDA indications

Dose/Route of Administration

Pregnancy, family planning & breastfeeding

Side effects and warnings (black box warnings are noted in bold)

Lemtrada®

(alemtuzumab)

Sanofi Genzyme

Approval: 2014 US; 2014 CAN, for the treatment of relapsing forms of multiple sclerosis, to include relapsing remitting disease and active secondary progressive disease, in adults. Because of Lemtrada's safety profile, the FDA recommends that this medication generally be reserved for people who have had an inadequate response to two or more MS therapies.

12 mg per day intravenous infusion (a needle placed in your vein) for five consecutive days, followed by 12 mg per day on three consecutive days one vear later

Pregnancy: May cause fetal harm

Most common side effects:

Rash, headache, fever, nasal congestion, nausea, urinary tract infection, fatigue, insomnia, upper respiratory tract infection, herpes viral infections, 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

Possible serious side effects:

- Serious, sometimes fatal, autoimmune conditions
- · Serious and life-threatening infusion reactions
- · Serious and life-threatening stroke
- Increased risk of cancer (malignancies)
- A serious kidney problem called anti-glomerular basement membrane disease
- Inflammation of the liver
- Overactivity of the immune system (hemophagogytic lymphohistiocytosis) that can be fatal
- A decrease in some types of blood cells
- Increased risk of infections
- Progressive multifocal leukoencephalopathy (PML), a rare brain infection that usually leads to death or severe disability

Intravenous infusion treatments				
Treatment (chemical name) Manufacturer FDA indications	Dose/Route of Administration Pregnancy, family planning & breastfeeding	Side effects and warnings (black box warnings are noted in bold)		
Novantrone® (mitoxantrone) Available only as a generic medication Approval: 2000 US for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (i.e., patients whose neurologic status is significantly abnormal between relapses)	12 mg/m² intravenous infusion (a needle placed in your vein) every 3 months. Lifetime cumulative dose limit of approximately 8–12 doses over 2–3 years (140 mg/m²) Pregnancy: May cause fetal harm when administered to a pregnant woman	Most common side effects: Nausea, hair loss, menstrual change, upper respiratory infection, urinary tract infection, mouth sores, irregular heartbeat, diarrhea, constipation, back pain, sinusitis, headache, blue-green urine Possible serious side effects: • Secondary acute myeloid leukemia (AML), a type of cancer, has been reported • Cardiotoxicity, specifically heart failure that can be fatal, that increases with the number of treatments Novantrone is rarely prescribed for MS. Read the medication guide for a comprehensive overview of side effects and risks associated with this medication.		
Ocrevus® (ocrelizumab) Genentech (a member of the Roche Group) Approval: 2017 US; 2013 CAN, for the treatment of relapsing forms of multiple sclerosis in adults, which include clinically isolated syndrome, relapsing-remitting disease (RRMS) and active secondary progressive disease, and primary progressive MS in adults.	600 mg intravenous infusion (a needle placed in your vein) every 6 months (first dose: 300 mg on day one and 300 mg 2 weeks later) Pregnancy: May cause fetal harm based on animal data	Most common side effects: Infusion reactions (most commonly itchy skin, rash, throat irritation, flushed face or fever, headache), which in rare instances may be life-threatening; increased risk of infections, including respiratory tract infections and herpes infections Possible serious side effects: • Hepatitis B reactivation that may cause serious liver problems including death • Decreased immunoglobulins (antibodies) • Risk of cancers (malignancies) including breast cancer Read the medication guide for a comprehensive overview of side effects and risks associated with this medication.		

Intravenous infusion treatments				
Treatment (chemical name) Manufacturer FDA indications	Dose/Route of Administration Pregnancy, family planning & breastfeeding	Side effects and warnings (black box warnings are noted in bold)		
Tysabri® (natalizumab) Biogen Approval: 2004 US, as a monotherapy (not in combination with any other MS disease-modifying treatment or other immune suppressant drugs) for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.	300 mg intravenous infusion (a needle placed in your vein) once every 28 days. Must take place in an approved infusion facility Pregnancy: May cause fetal harm based on animal data	Most common side effects: Headache, fatigue, joint pain, chest discomfort, urinary tract infection, lower respiratory tract infection, gastroenteritis, vaginitis, depression, pain in extremity, abdominal discomfort, diarrhea, and rash Possible serious side effects: Progressive multifocal leukoencephalopathy (PML), a rare brain infection that usually leads to death or severe disability. Risk of getting PML is higher if you have been infected by the John Cunningham Virus (JCV), have been on Tysabri for a long time, or have received certain medicines that can weaken your immune system Herpes infections that may increase the risk of getting an infection of the brain or the covering of the brain and spinal cord (encephalitis or meningitis) Weakened immune system and higher risk of infections Liver damage Low blood platelet counts		

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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 Society at **nationalMSsociety.org** or 1-800-344-4867.

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

About the National Multiple Sclerosis Society

The National MS Society, founded in 1946, funds cutting-edge research, drives change through advocacy, and provides programs and services to help people affected by MS live their best lives. Connect to learn more and get involved: **nationalMSsociety.org**, **Facebook**, **Twitter**, **Instagram**, **YouTube** or 1-800-344-4867.



National Multiple Sclerosis Society

nationalMSsociety.org

For information: 1-800-344-4867