Disease modifying drugs

a guide to treatments for relapsing MS

Multiple Sclerosis Trust

MS

MS Decisions

We hope you find the information in this book helpful. If you would like to speak with someone about any aspect of MS, contact the MS Trust information team and they will help find answers to your questions.

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Introduction

Disease modifying drugs (DMDs) are a group of treatments for people with relapsing multiple sclerosis.

There are 11 drugs approved for use by the NHS in the UK. Each drug offers a different combination of benefits and risks. This guide explains what the DMDs are, will help you explore your options and discuss starting or switching between one of the drugs with your MS team. This guide is not intended as a substitute for clinical advice.

The online resource MS Decisions (www.mstrust.org.uk/msdecisions) can be used alongside this guide. It includes a decision aid to help you narrow down the drugs, compare up to three DMDs side-by-side and get in-depth information on each drug.

You might be reading this guide because:

- you are looking for a general introduction to the DMDs so that you can get familiar with the options for treatment
- you have seen your MS team, talked about starting treatment and want to know a bit more
- your neurologist has given you a short list which you want to weigh up before your next clinic visit
- you are already on a DMD and considering switching to another one

Every effort has been made to ensure that the information in this book is accurate and up to date (October 2015). This is a rapidly developing area of MS treatment with regular changes to NHS eligibility for existing drugs and approval of new treatments.

MS Decisions will be updated as eligibility criteria are amended or new DMDs become available. See www.mstrust.org.uk/msdecisions for the most up to date information.

1. What is MS?

Multiple sclerosis is considered to be an autoimmune condition. The immune system generally knows which tissues are part of the person's body and which are foreign - eg a virus or bacterial infection - and needs attacking. In autoimmune conditions, for reasons which are not known, the immune system turns on the body's own tissue. In MS, the immune system attacks myelin - the fatty protein that forms an insulating sheath around nerve cells in the central nervous system (the brain and the spinal cord). This causes inflammation and damage to the myelin (called demyelination) which disrupts the way in which nerve messages are carried to and from the brain, leading to the symptoms of MS.

In the early stages of MS, it is possible for the body to repair damaged myelin (remyelination), or the central nervous system may re-route messages via different nerve pathways thereby avoiding damaged areas. However, if the nerves are left without the protection of myelin or the area of damage becomes too large, nerve fibres will be permanently destroyed and messages in that part of the central nervous system may become permanently blocked.

What are the different types of MS?

Although the effects of MS can vary greatly from person to person, there are three broad types. In addition, before being diagnosed with MS, people may experience a first episode of neurological symptoms, known as a clinically isolated syndrome.

Relapsing remitting MS (RRMS)

Most people are diagnosed with relapsing remitting MS. This means they will have periods when symptoms flare up

aggressively - known as a relapse, an attack or an exacerbation - followed by periods of good or complete recovery - a remission.

A relapse is the appearance of a new symptom or the reappearance of old symptoms that lasts more than 24 hours but more commonly, for a number of days or weeks. A relapse can last for considerably longer than that and may persist for weeks or months. The frequency of relapses, the severity of symptoms experienced and the length of the gap between attacks are unpredictable. It may sometimes be difficult to tell the difference between a relapse and day to day fluctuations in symptoms.

On average, people with relapsing remitting MS have one or two relapses a year. Although recovery from relapses may become less complete, the level of disability will remain more or less steady between relapses.

In the NHS, DMDs are approved for prescription according to how frequently you have been having relapses:

Active RRMS

- if you have had two relapses in the previous two years

Very active RRMS

- **highly active despite treatment** - if you continue to have relapses even though you've been taking a DMD for a year

OR

- **rapidly evolving severe** - if you have had two or more severe, or disabling, relapses in the previous year and show areas of new damage (lesions) on two consecutive MRI scans

Secondary progressive MS (SPMS)

Many people initially diagnosed with relapsing remitting MS find that over time, often many years, the frequency of relapses decreases and eventually stops but disability gradually increases. This is known as secondary progressive MS.

Some of the DMDs may be prescribed for people with SPMS who continue to have relapses.

Primary progressive MS (PPMS)

About 10% of people will be diagnosed with primary progressive MS in which disability increases from the outset with few or no relapses.

The DMDs have not been shown to offer any benefits for people with PPMS and none are routinely prescribed.

Clinically isolated syndrome (CIS)

When someone experiences their first episode of neurological symptoms it is referred to as a clinically isolated syndrome. Not everyone who experiences a CIS will go on to develop MS. For others it may be the first attack of what turns out to be MS. If MRI scans show brain lesions that are similar to those seen in MS then there is a greater risk of having further episodes which would lead to a diagnosis of MS.

Some of the DMDs may be prescribed after a first episode if there is considered to be a high risk of further episodes; the aim is to delay or even prevent a second attack.

2. What are disease modifying drugs?

Disease modifying drugs (DMDs) are a group of treatments for people with relapsing multiple sclerosis. DMDs work with different parts of the immune system to reduce the inflammation caused by MS to nerve cells in the brain and spinal cord.

What are the goals of treatment?

The main benefits of taking one of the DMDs are:

- fewer relapses
- any relapses you do have should be less severe (less likely to need steroids or a stay in hospital)
- reduce the build-up of disability which can occur if you don't recover completely from a relapse
- reduce areas of damage (lesions) in the brain and spinal cord which may help to reduce disability in the longer term

It may take up to six months for the drug to become fully effective so the effect may not be immediately obvious.

Inflammation does not always result in a relapse or visible symptoms. This silent activity may mean that although you are feeling well, there may still be changes caused by your MS that can only be seen on a brain scan. MRI scans show that taking a DMD can lead to fewer, smaller or no new areas of damage (lesions) in the brain and spinal cord. Treating the visibly active (relapses) as well as the silently active aspects of MS is a new goal that is emerging in MS treatment. This goal is often called no evidence of disease activity (NEDA). The aim is to reach a point where you are free of visible (relapses) and invisible (changes seen only on brain scans) MS disease activity.

DMDs are not able to repair nerve damage already caused by MS so they will not reverse any existing symptoms you may have. As they reduce inflammation and relapses they may prevent further symptoms from developing.

When used to treat clinically isolated syndrome, some of the DMDs have been shown to delay further episodes that would lead to a definite diagnosis of MS.

Some people with secondary progressive MS who continue to have disabling relapses may benefit from taking one of the DMDs.

None of the DMDs are recommended for people with secondary progressive MS who no longer have relapses or for people with primary progressive MS.

How effective are disease modifying drugs?

Large scale clinical trials compare the number of relapses in people taking a new drug with those taking an existing DMD or placebo (dummy drug). Trials may also measure the number of lesions seen on MRI scans and changes in disability which last for 3 months or longer.

Data from trials can be used to group the DMDs according to how effective they are. In this guide, we've followed broad categories recommended in guidelines published by the Association of British Neurologists (ABN):

- Category 1.1: **moderately effective** - reduces relapses by one third (30%)
- Category 1.2: **more effective** - reduces relapses by one half (50%)
- Category 2.0: **highly effective** - reduces relapses by two thirds (70%)

Do disease modifying drugs reduce long term disability?

Our understanding of how well DMDs work is mainly based on clinical trials of people receiving treatment for 2-4 years only. A number of studies have looked at long term effectiveness but there have been conflicting results as to whether DMDs slow down disability. As a result, there is still a lot of debate amongst neurologists and researchers about their long term effects. Though currently there is a lack of definitive evidence, there are now some studies which are helping to move us closer to a better understanding of the impact of DMDs on disability over time.

The UK Department of Health Risk-sharing Scheme, for example, has been conducting a study to observe more than 5,000 people taking one of the four injectable DMDs (Avonex, Betaferon, Copaxone, and Rebif), following them over 10 years. Levels of disability are the main focus of the study, not relapse rate. People with MS included in the study are being monitored for changes in their disability, compared to an untreated group.

A recently published paper shows that after six years, the group on treatment have developed lower levels of disability compared to the untreated group. The researchers conclude that all four drugs are effective in slowing the progress of the disease over the six year time period.

While these results provide encouraging evidence that DMDs slow down the progression of MS, there is currently no evidence that DMDs delay the onset of secondary progressive MS.

When is the right time to start treatment?

There is increasing evidence that it is best to begin treating RRMS early. This means starting DMDs soon after diagnosis. However, later is better than never, so if you are still having relapses after

having had MS for some time, you could still benefit as the treatments may help prevent further damage from occurring.

It is important to raise the topic of starting treatment soon after diagnosis with your MS team. If it isn't mentioned in your appointment, it is OK for you to bring it up.

What are the possible side effects of disease modifying drugs?

There are a number of side effects associated with each of the DMDs (see individual drugs for more detail), but not everyone will experience them. Most of the side effects are relatively mild and your MS team will give you advice on how to reduce their impact. Most people find that side effects ease after the first month or two as their body adapts to the drug. A few people find side effects continue to cause problems so that they have to change or stop treatment.

Some of the DMDs are associated with less common but potentially serious and life-changing side effects. Your MS team will take steps to minimise the risks if you are taking one of these drugs, such as giving advice on warning signs, carrying out additional tests and check-ups. If there is any cause for concern, your MS team will step in quickly. Despite the reassurance of regular monitoring, some people may feel that they are unwilling to take the risk of developing serious side effects. Others may feel that the benefits of a drug outweigh the risks.

3. Making your choice

The decision to start a DMD should be made in partnership with your MS team. They have knowledge and experience in managing MS and can advise on which treatments might be right for you and your MS. You are the expert on your own life and what matters to you. Bringing together your preferences with the experience of your MS team can help you make a choice that is the best balance between the effectiveness of a drug and how well it suits your circumstances.

This section aims to help you think about your own views, preferences and attitude to risk. Knowing about the available options and what is important to you will help you make an informed choice.

It is up to you how much you want to be involved in choosing your treatment. You might want your neurologist and MS nurse to take the lead or you might prefer to be very involved.

Considering what is important to you

Starting any DMD is a long term commitment, so it is important you have as much information as you feel you need to make your decision.

As you go through this section, you might want to think about:

- What is important to you?
- What do you want to achieve by taking one of the DMDs?
- How do you usually make decisions? On your own or do you often rely on advice from others?
- Are you a risk taker or more cautious?
- Do you like to get background information and weigh up the pros and cons or do you prefer to rely on gut instinct?

Your personal circumstances and commitments

Starting treatment with one of the DMDs is likely to have some impact on your life. At the very least you need to take it at the prescribed times. For some of the DMDs there are additional commitments you need to make. Some require you to go to the hospital for treatment, some have regular blood tests and others might need to be stored in a particular way.

Below are a number of topics and questions you might think about when you consider your treatment options. They will help you work out how much these factors may influence your choice.

Family

Are you considering starting a family soon? As none of the DMDs are recommended for use during pregnancy, this will probably have an impact on when you start treatment. You would need to discuss your options in more detail with your MS team. See Sections 5 and 6 for more details.

If you already have children, do you have a support network that could help if you need to attend clinics at a time when you also have family commitments? Will taking a drug have an impact on your daily routines?

Work

If you travel a lot with work, work unusual hours or on shifts, what impact might that have? Could you take your doses at the right times? How easy would it be for you to attend regular check-ups?

You may not have told your employer about your MS diagnosis, especially if your MS is not having an impact on your work. If you need time off for treatment or tests, you might need to think about how you can arrange your appointments, or find a way you can have the necessary time off without raising concern if you are not yet ready to tell people.

Holidays

Do you like remote or extended holidays? Or are you planning on going travelling for a long period? There are some drugs that might be more convenient for your lifestyle, but you might need to make arrangements with your MS team to ensure you can take your medications with you so that you can continue treatment uninterrupted.

Transport

If you rely on public transport or for someone else to take you to appointments, you might like to consider how easy or cost effective it would be to get to the clinic where your treatment or monitoring might take place.

Health

Do you have any other health conditions? It is important to let your MS team know about any other conditions you may have. If you have other health issues or take certain drugs some of the DMDs may not be suitable for you or you may need extra tests or monitoring. You may also want to consider whether a potential DMD side effect might aggravate your pre-existing condition.

Storage and supply

As some of the drugs need to be stored in the fridge, you might need to consider if this is possible for you. Do you have enough space in your current fridge? If you share a house with others, you may only have limited space or you might not be comfortable storing your drugs in the fridge. If you have small children, could you store your drugs in the fridge on a shelf where they would be out of their reach?

The consequences of no treatment

As MS is such a variable condition it is difficult to know how your own MS will develop, predict how many relapses you will have and when these will occur. If you have had very few relapses or you currently feel well, you may feel that you do not want to start

drug treatment. You may want to look to other options or you may wish to continue life as you were before.

As explained in Section 2, relapses may be just the tip of the iceberg when it comes to MS, and there can be other activity going on beneath the surface that you might not be aware of. Without DMD treatment you may be at risk of further relapses and permanent nerve damage.

Some people decide to try managing their MS through lifestyle changes to see if, for example, improving diet, exercising or taking complementary medicines might help. Ensuring you are eating a balanced diet, taking regular exercise and not smoking can help you be as healthy as possible and reduce your risk of developing other health conditions too. **However, there is no evidence that these lifestyle changes alone will make a difference to the course of MS. It is generally accepted that these lifestyle changes are complementary to drug treatment and part of a holistic management of MS, but they are not a substitute for drug treatment.**

It is important to remember even if you decide you do not want to start treatment now, you can change your mind later. If your MS team has suggested you start DMD treatment now but you would rather wait and see what happens or would like to try something else first, discuss your thoughts and decision with them. Perhaps you can agree to try out your way first and review how active your MS is after a set period, to see if lifestyle changes are working for you or if you wish to reconsider your DMD options.

Weighing up the pros and cons

The pros and cons of each of the treatment options should form part of your discussion with your MS team. Pros will include the benefits you expect to gain from taking one of the DMDs and things you consider to be an advantage such as the ease of

taking a particular drug. Cons may include the risk of certain side effects or the inconvenience of going to a clinic for regular tests. Each person will have very different ideas of what they consider to be pros or cons.

Sometimes you may need to make trade-offs. To receive the benefits of a particular treatment you might need to be willing to accept the possibility of particular risks or the inconvenience of going for regular treatment or tests.

Guidance from your MS team

Your MS team will tell you if you are eligible for DMDs and if so which ones would be suitable for you and your MS. They will make recommendations based on how active your MS has been, the number of relapses you have had and how these have affected you. When prescribing a DMD, your MS team has to work within strict NHS eligibility criteria which define the type of MS the drug can be used for. DMDs can only be prescribed by a neurologist or, in some areas, by a consultant nurse.

Like you, your MS team will have their own opinions and views on the best course of action to take. They may weigh up the pros and cons of each option in a different way to you and will have a different perspective. Some might suggest a riskier course of action for bigger benefits and some may recommend a more cautious approach.

Your MS team is there to support you in the management of your MS, so do take account of their advice but feel free to ask them questions and explain your own preferences if you have any concerns. You can find sample questions to ask on the back cover of this book.

If after further discussions, you are not happy with the treatment choices you are offered, you are entitled to ask for a second opinion. Your GP can refer you for a second opinion; although there is no legal right to a second opinion, requests are usually accepted.

4. Starting, switching and stopping

Starting treatment

Will I have to pay for the drug?

If you are eligible for NHS treatment, you will not have to pay for the drug itself. In England, you may have to pay the standard prescription charge.

How will I get my supply of the drug?

Depending on which drug you are prescribed, you may either collect it from the hospital pharmacy, receive it in hospital as a day patient or inpatient, or have it delivered to your home or agreed address by a designated home delivery company. Your MS team can explain the options available locally.

What support will I receive when I start taking my DMD?

Before you start taking a DMD your MS team will explain how to take the drug, how to manage any side effects and who to contact if you should have problems. If you are starting an injectable treatment your MS nurse will show you how to do injections. Your MS team will also make regular appointments with you to check how you are doing on treatment.

How long do I need to be on treatment?

DMD treatment is a long term commitment measured in years, but you will be regularly reviewed by your MS team to see if the treatment is still effective for your MS. Your MS team will assess how you are managing any side effects and will check for complications.

Can I take a break from treatment?

It is not recommended that you take a break from treatment once you have started as keeping a steady level of drug in

your body is important for it to work properly. There may be times when you or your MS team think taking a break might be appropriate, for example if you are hoping to get pregnant, but you should discuss the potential benefits and risks of doing this with your MS team before you stop taking your drug.

Switching treatment

Is it possible to change which drug I take later on?

It is possible to change drugs, although this will be a decision that is made between you and your MS team. You may need to change drugs if you have continued to experience relapses, if your brain scans show that your MS is active or if you are experiencing persistent and unmanageable side effects.

What happens if I don't respond to treatment?

All of the DMDs take several months to start working to reduce the number of relapses you have. If after a period of time you experience the same number of relapses, or your relapses are as severe as or worse than before treatment or your brain scans show that your MS remains active, the drug might not be working for you. Your MS team may suggest changing (switching) to another DMD, most probably one that is more effective. This is known as escalating treatment.

What happens if my treatment stops working?

If, having been on treatment for a while with your MS well controlled, you then notice that things are changing, the treatment may have stopped working for you. You may have more relapses, there may be more changes on your brain scans or you might find that you are having more problems with walking or other symptoms. There are several reasons why this may happen. The body's natural defences can develop antibodies against some of the DMDs, reducing or 'neutralising' their effect. It might also be that the nature of your MS has changed. If you notice any changes, contact your MS team to discuss your options. They may suggest changing to another DMD.

Stopping treatment

Can I stop treatment?

If you do not feel the treatment is effective or you are struggling with side effects then you can stop the treatment. This should only be done following discussion with your MS team. They may be able to suggest an alternative drug you may wish to try first before stopping treatment altogether.

Is it likely my MS will get worse if I stop treatment?

If you stop treatment there is a greater risk that you will have a relapse. As MS is unpredictable and everyone's experience is different, it is impossible to predict to what extent your MS may get worse if you stop treatment.

Could my MS team decide to stop my DMDs – if so why?

If your MS team conclude your treatment is no longer working or you develop serious complications from the drug then they may suggest you stop treatment. Even if the drug has been effective in the past, there may come a time when treatment is no longer effective or you are at too high a risk of the complications to continue. Alternatively the nature of your MS may have changed. A proportion of people will develop secondary progressive MS meaning they have fewer or no relapses but have a gradual increase in disability. The progressive phase is thought to be caused by permanent loss of nerves rather than new inflammation, so the DMD drugs are not effective or useful in this stage.

Your team should discuss the reasons why treatment may need to be stopped, give advice on an appropriate time to do this and give support throughout the process.

5. Conception, pregnancy and breastfeeding

Conception

I'm a woman with MS, can I take DMDs while we try for a baby?

There is a limited amount of information available about the effect on conception or the unborn child when the mother is taking a DMD. As the effect is unknown, it is usually advisable not to start treatment if you are considering starting a family soon, but you should discuss your own situation with your MS team to determine what course of action is best for you.

I'm a man with MS, can I take DMDs while we try for a baby?

There is very limited information concerning the impact of DMDs on conception or the unborn child when the father is taking a DMD. The available information suggests that the use of some DMDs by the father has no adverse effect on the baby, and that there are no differences between babies born to men with MS taking a DMD and those that were not. However as there is no published data on some of the DMDs you should discuss your situation and treatment options with your MS team.

Pregnancy

Can I take DMDs during pregnancy?

DMDs have not been studied in pregnant women and so none are considered safe to use during pregnancy. Consequently women are usually advised to stop treatment. Many women find that their MS improves during pregnancy and studies have shown relapses are less likely. You should discuss any plans for pregnancy with your MS team, so they can advise you when and how you should stop treatment based on how active your MS has been.

What should I do if I become pregnant while on treatment?

If you find yourself pregnant while taking a DMD you should contact your MS team to discuss whether or not to come off of treatment.

Breastfeeding

Can I breastfeed if I am taking a DMD?

DMDs have not been studied in breastfeeding women and there is limited information available. As the effect on the child is unknown, you should normally stop treatment until you have finished breastfeeding. There is an increased risk of having a relapse in the three months after childbirth. If your MS was particularly active before pregnancy, your MS team may be concerned about your risk of having a relapse after childbirth and may recommend that you discontinue breastfeeding and opt for bottle feeding so that you can begin DMDs again.

6. Disease modifying drugs

Beta interferons

Avonex	Betaferon	Extavia	Plegridy	Rebif
Interferon beta 1a	Interferon beta 1b	Interferon beta 1b	Peg-interferon beta 1a	Interferon beta 1a
Injected into a muscle	Injected under the skin	Injected under the skin	Injected under the skin	Injected under the skin
Once a week	Every other day	Every other day	Once a fortnight	Three times a week
Approved since 2002	Approved since 2002	Approved since 2009	Approved since 2015	Approved since 2002

You self-inject the beta interferons, either under the skin (subcutaneously) on into a muscle (intramuscular). They reduce the number of relapses you have and any relapses you do have should be less severe.

Beta interferons are all moderately effective (category 1.1) DMDs; they reduce the number of relapses you have by about one third (30%).

MRI scans show that people taking one of the beta interferons have fewer, smaller or no new areas of active MS (lesions). Beta interferons may also slow down the build-up of disability associated with MS.

Who can take beta interferons?

Avonex	Betaferon	Extavia	Plegridy	Rebif
Active relapsing remitting MS	Active relapsing remitting MS	Active relapsing remitting MS	Active relapsing remitting MS	Active relapsing remitting MS
Clinically isolated syndrome	Clinically isolated syndrome	Clinically isolated syndrome		Clinically isolated syndrome

All of the beta interferons can be prescribed for adults with active relapsing remitting MS.

Some of the beta interferons can be prescribed for people with secondary progressive MS who continue to have disabling relapses. Speak to your MS team for further information.

Some of the beta interferons can also be prescribed for people who have had a first episode of neurological symptoms (clinically isolated syndrome) and have a high risk of developing MS (see table).

Contraindications

It's important that you tell your MS team if you have any health problems or are taking other medicines. Beta interferons may not be suitable if you have severe depression or suicidal thoughts.

Conception and pregnancy

Pregnancy is not recommended during treatment. If you are trying for a family, talk to your MS nurse or neurologist about whether you should continue to take one of the beta interferons until you are pregnant. If you become pregnant while taking one of the beta interferons, contact your MS team. Your neurologist or MS nurse may recommend you stop taking it.

How do I take beta interferons?

You self-inject the beta interferons either under the skin or into a muscle. Each of the beta interferons are supplied in a number of formats to make injections easier - your MS nurse can explain the different injection devices and help you choose the one most appropriate for you.

Your MS nurse will show you how to do the injections, discuss the practicalities and offer advice or training and ongoing support if you should need it.

To give your body a chance to get used to the drug and reduce the impact of side effects, your doctor or MS nurse may suggest you start on a lower dose, increasing to a full dose over time.

What side effects could I get with beta interferons?

Common side effects include:

- flu-like symptoms, such as headache, muscle ache and stiffness, chills or fever, following an injection
- injection site reactions

You are more likely to have these side effects when you first start taking one of the beta interferons. Most people have mild to moderate side effects which tend to go away over time.

A neurologist or MS nurse may suggest ways to reduce these side effects including:

- to help with flu-like symptoms, try changing the time of day when you do your injection so that you sleep through the worst of the side effects
- to help reduce fever, paracetamol or ibuprofen can be taken before the injection and at four to six hour intervals after the injection, as required

Common side effects (affecting more than 1 person in 100)

- flu-like symptoms
- injection site reactions
- headache
- decrease in white blood cells
- difficulty sleeping
- diarrhoea, nausea and vomiting
- depression
- hair loss

Assessment before treatment

Before starting a beta interferon, you should have blood tests to measure blood cell counts and check liver function.

Assessment during treatment

Once you've started treatment, you'll have blood tests to measure blood cell counts and monitor liver function, generally every three months for the first year, then less frequently. Depending on local practice, the tests may be carried out at a local GP surgery or it may be necessary to attend a hospital clinic.

How do the beta interferons work?

Interferons are proteins that occur naturally in the immune system. It is thought that beta interferon acts by reducing both inflammation and the immune response that is attacking the body's own myelin.

Additional information

Supply of Avonex, Plegridy and Rebif must to be stored in the fridge.

Copaxone 

Other names: glatiramer acetate

You self-inject Copaxone under the skin either daily or three times a week to reduce the number of relapses you have; any relapses you do have should be less severe.

Copaxone is a moderately effective (category 1.1) DMD; it reduces the number of relapses you might have by about one third (30%).

MRI scans show that people taking Copaxone have fewer, smaller or no new areas of active MS (lesions).

Who can take Copaxone?

Copaxone can be prescribed for adults with active relapsing remitting MS.

Copaxone can also be prescribed for people who have had a first episode of neurological symptoms (clinically isolated syndrome) and have a high risk of developing MS.

Copaxone taken daily has been approved for use on the NHS since 2002. Copaxone three times a week has been approved since 2015.

Conception and pregnancy

Pregnancy is not recommended during treatment.

If you are trying for a family, talk to your MS nurse or neurologist about whether you should continue to take Copaxone until you are pregnant.

If you become pregnant while on Copaxone, your neurologist or MS nurse may recommend you stop taking it.

How do I take Copaxone?

You self-inject Copaxone under the skin. Two doses are available: one for daily injections and another for three times a week injections. Copaxone is supplied in single-use, pre-filled syringes. An automatic injection device is also available to make injections easier.

Your MS nurse will show you how to do the injections, discuss the practicalities and offer advice or training and ongoing support if you should need it.

What side effects could I get with Copaxone?

Common side effects include:

- injection site reactions such as lipoatrophy (leading to permanent indentations in the skin)
- redness, swelling, itching or some pain at the site.

Occasionally, some people may experience a reaction, known as the immediate post-injection reaction (IPIR), shortly after injection. This may cause flushing, chest tightness, shortness of breath and palpitations. This reaction can last 15-30 minutes, will ease without any treatment and doesn't cause long-term problems. If symptoms last longer than 30 minutes, contact your doctor immediately or go straight to the A&E department of your nearest hospital.

Common side effects (affecting more than 1 person in 100)

- injection site reactions
- lipoatrophy (indentations in the skin)
- headache
- depression, anxiety
- nausea

- feeling weak
- chest pain, other pain
- swollen lymph nodes
- gastrointestinal changes

Assessment before treatment

Blood tests are not generally required before starting treatment with Copaxone.

Assessment during treatment

There is no need for routine blood tests during treatment, but your MS nurse will arrange regular appointments to review how you are coping with Copaxone.

How does Copaxone work?

Copaxone is a synthetic combination of four amino acids, resembling the myelin protein that surrounds nerve fibres. It is thought to reduce the immune response that attacks myelin.

Additional information

Supply of Copaxone must to be stored in the fridge.

Aubagio

Other names: teriflunomide

You take Aubagio as a pill once a day to reduce the number of relapses you have; any relapses you do have should be less severe.

Aubagio is a moderately effective (category 1.1) DMD; it reduces the number of relapses you might have by about one third (30%).

MRI scans show people taking Aubagio have fewer, smaller or no new areas of active MS (lesions).

Aubagio may also slow down the build-up of disability associated with MS.

Who can take Aubagio?

Aubagio can be prescribed for adults with active relapsing remitting MS. NHS approval excludes people who have very active MS (this covers highly active despite treatment with another DMD or rapidly evolving severe relapsing remitting MS).

Aubagio has been approved for use on the NHS since 2014.

Contraindications

It's important that you tell your MS team if you have any health problems or are taking other medicines. Aubagio may not be appropriate if you have existing medical conditions including: severe liver problems, serious problems affecting the immune system (eg AIDS) and significant problems affecting bone marrow or reduced blood cell counts (eg anaemia, leucopenia, neutropenia or thrombocytopenia).

Conception and pregnancy

You must not become pregnant while taking Aubagio.

Based on data in animal studies, there is an increased risk of having a baby with birth defects if Aubagio is taken during pregnancy. Aubagio remains in the blood for a long time after stopping treatment, so this risk may continue for up to two years.

Women of childbearing age must use an effective method of contraception during treatment and for two years after stopping Aubagio.

Women who suspect that they are pregnant while taking Aubagio, or in the two years after stopping treatment, should contact their GP immediately for a pregnancy test. If the test confirms pregnancy, the blood levels of Aubagio can be reduced rapidly to safe levels by taking certain medicines (cholestyramine or activated charcoal).

Women who wish to become pregnant should stop taking Aubagio. The removal of Aubagio can be speeded up using the medicines described above. A blood test can confirm that the levels of Aubagio are low enough that it is safe to attempt to become pregnant.

How do I take Aubagio?

You take Aubagio as a pill, once daily.

What side effects could I get with Aubagio?

Common side effects include:

- feeling sick
- diarrhoea
- hair thinning

You are most likely to have these side effects when you first start taking Aubagio but they generally improve in the following months.

Common side effects (affecting more than 1 person in 100)

- increased levels of liver enzymes
- feeling sick
- diarrhoea
- hair thinning and loss

Assessment before treatment

Before starting Aubagio, you should have blood tests to measure blood cell counts and check liver function. Blood pressure will also be checked.

As Aubagio must not be taken during pregnancy, women of child-bearing age may be offered a pregnancy test.

Assessment during treatment

Once you've started treatment you'll have blood tests to monitor liver function, generally every 2 weeks for the first 6 months and every 8 weeks thereafter. Depending on local practice, the tests may be carried out at a local GP surgery or it may be necessary to attend a hospital clinic.

Blood pressure and blood cell counts will also be monitored periodically during treatment.

How does Aubagio work?

The mechanism of action of Aubagio is not completely understood, but it is thought that the main effect is to stop certain immune cells from multiplying. This results in lower numbers of both B-cells and T-cells, two types of white blood cell involved in the damage associated with MS.

Tecfidera

Other names: dimethyl fumarate

You take Tecfidera as a pill twice a day to reduce the number of relapses you have; any relapses you do have should be less severe.

Tecfidera is a more effective (category 1.2) DMD; it reduces the number of relapses you might have by about one half (50%).

MRI scans show that people taking Tecfidera have fewer, smaller or no new areas of active MS (lesions).

Tecfidera may also slow down the build-up of disability associated with MS.

Who can take Tecfidera?

In England, Wales and Northern Ireland, the drug can be prescribed for adults with active relapsing remitting MS. NHS approval excludes people who have very active MS (this covers highly active despite treatment with another DMD and rapidly evolving severe relapsing remitting MS).

In Scotland, Tecfidera is approved for adults with relapsing remitting MS.

Tecfidera has been approved for use on the NHS since 2014.

Conception and pregnancy

Tecfidera is not recommended during pregnancy.

If you are trying for a family, talk to your MS nurse or neurologist about whether you should continue to take Tecfidera until you are pregnant.

If you become pregnant while on Tecfidera, your neurologist or MS nurse may recommend you stop taking it.

How do I take Tecfidera?

You take Tecfidera as a pill, twice daily with food.

To give your body a chance to get used to the drug and reduce the impact of side effects, you start on a low dose for the first week, increasing to the full dose in the second week.

What side effects could I get with Tecfidera?

Common side effects include:

- flushing and feeling hot
- gastrointestinal upset - diarrhoea, feeling sick, stomach pains

You are more likely to have these side effects when you first start taking Tecfidera (mostly during the first month). Most people have mild to moderate side effects which tend to go away over time.

A neurologist or MS specialist nurse may suggest ways to reduce these side effects including:

- reducing the dose temporarily, returning to full dose within one month
- taking aspirin before each dose to prevent flushing (long term use of aspirin is not recommended)
- taking doses on a full stomach to reduce gastrointestinal upset – experience suggests this needs to be a balanced meal rather than a light snack

Common side effects (affecting more than 1 person in 100)

- flushing and feeling hot
- gastrointestinal upset (feeling sick, diarrhoea, abdominal pain, vomiting, indigestion)
- decrease in white blood cells

- rash
- increased levels of liver enzymes
- ketones and protein in urine

Cases of brain infection (progressive multifocal leukoencephalopathy, PML) have been reported for people taking Tecfidera. The risk of developing PML on Tecfidera is considered very low but if you are worried discuss your concerns with your MS team.

Assessment before treatment

Before starting Tecfidera, you should have blood and urine tests to measure blood cell counts and to check liver and kidney function.

Assessment during treatment

Once you've started treatment you'll have blood and urine tests at 3 months, 6 months and then every 6 to 12 months thereafter. These tests monitor your blood cell counts and liver and kidney function. Depending on local practice, you may be able to have the tests at your GP surgery or you may need to attend a hospital clinic.

How does Tecfidera work?

The way Tecfidera works is not fully understood, but laboratory studies suggest that it may work in two ways:

- reduces the inflammation caused when the immune system attacks myelin, resulting in less damage to myelin
- protects nerve cells from damage caused by chemicals released during the immune attack

Additional information

Capsule contains beef gelatin.

Gilenya

Other names: fingolimod

You take Gilenya as a pill once a day to reduce the number of relapses you have; any relapses you do have should be less severe.

Gilenya is a more effective (category 1.2) DMD; it reduces the number of relapse you might have by about one half (50%).

MRI scans show that people taking Gilenya have fewer, smaller or no new areas of active MS (lesions).

Gilenya may also slow down the build-up of disability associated with MS.

Who can take Gilenya?

Across the UK, Gilenya can be prescribed if you are still having relapses after taking one of the beta interferon DMDs for at least one year.

In England, Gilenya can also be prescribed if you are still having relapses after taking Copaxone or Tecfidera or if you have a high risk of developing PML while taking Tysabri.

In Scotland, Gilenya can be prescribed if you are still having relapses after taking any one of the DMDs or if you have very active MS (two or more disabling relapses in one year and MRI evidence of new areas of MS activity).

Gilenya has been approved for use on the NHS since 2012.

Contraindications

It's important that you tell your MS team if you have any health problems or are taking other medicines. You should not start Gilenya if you have a lowered immune response, have a severe

infection such as hepatitis or tuberculosis, have active cancer (except for some types of skin cancer) or severe liver problems.

If you have certain conditions, including heart problems, liver disease or a condition affecting your eyes, you may need additional medical assessment before Gilenya is prescribed and may need additional monitoring during treatment.

Conception and pregnancy

You must not become pregnant while taking Gilenya.

Based on data in animal studies, there is an increased risk of having a baby with birth defects if Gilenya is taken during pregnancy.

Women who wish to become pregnant should stop taking the drug but continue to use effective contraception for two months to ensure that blood levels of Gilenya are low enough for it to be safe to become pregnant.

How do I take Gilenya?

You take Gilenya as a pill, once daily.

The first dose is taken in a hospital or clinic under medical supervision as Gilenya is known to cause temporary changes in heart rate, heart beat and blood pressure. These symptoms are monitored for six hours.

Unless there are problems, further doses of Gilenya are taken at home.

What side effects could I get with Gilenya?

Common side effects include:

- cough
- headache

- back pain
- diarrhoea
- increased risk of infections
- increased levels of liver enzymes
- decrease in white blood cells

Gilenya may also cause a less common side effect (affecting less than 1 in 100 people) macular oedema, a swelling in the back of the eye which can affect vision.

Cases of brain infection (progressive multifocal leukoencephalopathy, PML) have been reported for people taking Gilenya. The risk of developing PML on Gilenya is considered very low but if you are worried discuss your concerns with your MS team.

Assessment before treatment

Before starting Gilenya, you will have tests to check for immunity against the virus that causes chicken pox and your blood pressure and pulse will be measured. You should have blood tests to measure blood cell counts and check liver function. If you have a pre-existing health condition which affects the eye, such as diabetes, you may also have an eye examination. Women of child-bearing age may be offered a pregnancy test.

Assessment during treatment

Once you've started treatment, you'll have blood tests to measure blood cell counts and monitor liver function and your blood pressure will be measured.

After about 3-4 months of starting treatment an eye test may be recommended to monitor for macular oedema.

How does Gilenya work?

Gilenya binds to the surface of white blood cells (lymphocytes) in the blood, and these cells are then trapped in the lymph glands,

which prevents the lymphocytes from crossing into the central nervous system and causing inflammation and damage.

Additional information

Capsule contains beef gelatin.

Tysabri

Other names: natalizumab

You take Tysabri as an intravenous infusion (drip) once every four weeks to reduce the number of relapses you have; any relapses you do have should be less severe.

Tysabri is a highly effective (category 2.0) DMD; it reduces the number of relapses by about two thirds (70%).

MRI scans show that people taking Tysabri have fewer, smaller or no new areas of active MS (lesions).

Tysabri may also slow down the build-up of disability associated with MS.

Who can take Tysabri?

Tysabri can be prescribed if you have very active relapsing remitting MS, which is defined as two or more relapses in one year, with signs of increasing or new lesions between two consecutive MRI scans.

Tysabri has been approved for use on the NHS since 2007.

Contraindications

It is important that you tell your MS team if you have any health problems or are taking other medicines. Your neurologist will need to know if you have previously taken other drugs which suppress the immune system (for example mitoxantrone, azathioprine, cyclophosphamide or methotrexate).

Conception and pregnancy

Pregnancy is not recommended during treatment with Tysabri.

If you are trying for a family, your MS team may recommend

remaining on Tysabri until conception, then review whether you should continue treatment during pregnancy based on how active your MS has been and the risk that you might have a significant relapse.

How do I take Tysabri?

You take Tysabri as an intravenous infusion (a small tube placed in a vein, with the treatment infused via a pump) once every four weeks. This is generally done in a hospital infusion clinic and takes 2 to 3 hours.

What side effects could I get with Tysabri?

Common side effects include:

- headache
- dizziness
- itchy skin rash
- increased risk of infections

Treatment with Tysabri may increase the risk of progressive multifocal leukoencephalopathy (PML), an uncommon brain infection that can lead to severe disability or even death. PML is caused by a mutation of the JC virus, a common infection completely unrelated to MS. It is normally kept under control by the immune system, causing no problems. If your immune system is weakened and your body less able to fight an infection, which may occur when you are taking Tysabri, the JC virus can become active and cause inflammation and damage to the brain.

A blood test can detect the JC virus and give an indication of the risk that you might develop PML. Other factors which increase the risk of PML include previous treatment with an immunosuppressant drug (for example azathioprine,

cyclophosphamide, mitoxantrone or methotrexate) and the length of time you have been taking Tysabri. Your neurologist or MS specialist nurse will discuss the implications of the blood test and how it may affect the benefits and risks of treatment.

When you start taking Tysabri you will be informed of the early signs and symptoms of PML. These can be similar to an MS relapse, so it is important to report any new or worsening symptoms. If PML is suspected at any point during treatment, the drug will be discontinued immediately.

Assessment before treatment

Blood tests will be performed before starting treatment to determine whether you have been previously infected by the JC virus. You should have blood and urine tests to measure blood cell counts and to check liver and kidney function. It is also important that you have had a recent (usually within 3 months) MRI scan.

Assessment during treatment

Prior to each infusion, blood pressure, temperature and pulse rate will be taken. Monitoring will also take place during the infusion and for one hour after to check for any serious allergic reaction (hypersensitivity).

If a previous blood test found no evidence of a JC virus infection, you should have further blood tests because it is possible to be infected at any time. It is recommended that blood tests are repeated every six months.

How does Tysabri work?

Tysabri binds to immune cells in the blood stream, preventing them from passing through blood vessel walls and into the central nervous system where they can damage nerves.

Lemtrada

Other names: alemtuzumab, Campath

You take Lemtrada as an intravenous infusion (drip) in two treatment courses, twelve months apart. It reduces the number of relapses you have.

Lemtrada is a highly effective (category 2.0) DMD; it reduces the number of relapses you have by about two thirds (70%).

MRI scans show that people taking Lemtrada have fewer, smaller or no new areas of active MS (lesions).

Lemtrada may also slow down the build-up of disability associated with MS.

Who can take Lemtrada?

Lemtrada can be prescribed for adults with active relapsing remitting MS and for very active relapsing remitting MS.

Lemtrada has been approved for use on the NHS since 2014.

Conception and pregnancy

Pregnancy is not recommended during treatment and for four months after a treatment course with Lemtrada. If you plan to start a family discuss your specific circumstances with your MS team.

Women of child-bearing age must use effective contraception during and for four months after a treatment course.

If you become pregnant after treatment with Lemtrada and experience a thyroid disorder during pregnancy, extra caution is needed as thyroid disorders could be harmful to the baby.

How do I take Lemtrada?

You take Lemtrada as two treatment courses of intravenous (iv) infusions.

- the first course consists of iv infusions on five consecutive days
- the second course is taken 12 months later and consists of iv infusions on three consecutive days

In general you will be admitted as a hospital inpatient for the duration of each treatment course.

Most of the people who take Lemtrada will not require additional treatment courses; if you continue to experience relapses you may be offered further treatment courses.

What side effects could I get with Lemtrada?

Common side effects include:

- infusion-related reactions such as headache, rashes, fever and nausea.

Most people treated with Lemtrada are affected by these reactions but they are generally mild to moderate and short-lived. You will be given additional medications to reduce these infusion-related reactions.

- infections including coughs, colds, chest infections and herpes virus infections (such as cold sores or shingles)

Lemtrada suppresses the immune system for some time after a treatment course so people will be more vulnerable to infections such as colds and viruses. To reduce the risk of herpes infections, an antiviral medication should be taken starting from the first day of infusion and continued for at least one month.

Three serious side effects have been reported from clinical trials:

- overactive or underactive thyroid gland leading to thyroid disorders, affecting 300 in 1000 people
- idiopathic thrombocytopenic purpura (ITP), a serious disorder which prevents blood from clotting, affecting 10 in 1000 people
- kidney problems, affecting 3 in 1000 people

These side effects are potentially serious but they are treatable if caught early enough. People taking Lemtrada will be informed of the early signs and symptoms of these side effects.

Assessment before treatment

Before starting Lemtrada, you should have blood and urine tests to measure blood cell counts and to check the function of the thyroid gland and kidneys. You should also be tested for immunity against the virus that causes chickenpox and offered vaccination if you have not previously been exposed to the virus.

Assessment during treatment

Because of the serious nature of the potential side effects, it is vital that you have monthly blood and urine tests for four years after your last treatment course to monitor blood cell counts and to check the function of the thyroid gland and kidneys. Depending on local practice, tests may be carried out at a local GP surgery or it may be necessary to attend a hospital clinic.

How does Lemtrada work?

Lemtrada works by binding to and killing immune cells (lymphocytes or white blood cells) which are involved when the immune system attacks myelin. It is thought that the cells which grow back after treatment do not cause damage to nerves.

7. Further sources of information and support

MS specialist nurse

An MS specialist nurse will talk through your options, give practical advice and training and provide support as you start and through the course of treatment. This usually takes place at a nurse-led disease modifying drug clinic. To find an MS specialist nurse, contact the MS Trust information service or visit the map of MS services www.mstrust.org.uk/map

MS Trust publications

Website

- *MS Decisions*
  An online guide to the disease modifying drugs. It includes a guide to decision making, straightforward answers to frequently asked questions and an interactive tool to help explore and compare the options www.mstrust.org.uk/msdecisions
- *Drugs in development*
  Provides information on drug therapies in clinical development www.mstrust/did

Books

- *MS Explained*

Factsheets

- *Clinically isolated syndrome (CIS)*

MS Trust information service

The MS Trust information service is available to answer any questions about MS. Contact by Freephone 0800 032 3839 (Monday to Friday 9-5) or email infoteam@mstrust.org.uk

Electronic Medicines Compendium (eMC)

- www.medicines.org.uk
  Patient information leaflets for all the DMDs

About the authors

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The MS Trust is a UK charity for people with MS, their family and friends. The MS Trust Information Service offers a personalised enquiry service; produces a wide range of publications including Open Door, a quarterly newsletter; and provides web based information.

Thank you to

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Please contact the MS Trust information team if you would like any further information about the reference sources used in the production of this publication.

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Questions for your MS team

To get the most from discussions with a neurologist or MS nurse, it is helpful to prepare in advance.

- Make a list of the questions you want to ask
- Keep a record of any relapses you have

You might find it helpful to take a friend or family member along with you to appointments. They can support you or take notes, to help ensure that you ask all of the questions you want to ask and get the answers that are important to you.

- What type of MS do I have?
- How active is my MS?
- What are my treatment options?
- What are the pros and cons of each option?
- Why should I consider taking this particular DMD?
- How effective is this DMD?
- What tests will I need before I start and when I'm taking this DMD?
- What are the side effects or risks associated with this DMD?
- What can be done to reduce the impact of side effects or the risks?
- Does this DMD affect other treatments I am taking?
- How long will I need treatment for?
- How will I know if the treatment is working?
- What will happen if I don't have any treatment?
- Is there anything I can do to help myself?
- Where can I go for more information?

For more tips on how to make the most of appointments visit www.mstrust.org.uk/making-most-appointments

We hope you found this book useful.

Could you make a difference for even more people living with MS?

It's only thanks to donations from people like you that the MS Trust can continue to provide free, reliable, practical MS information.

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Thank you

Drug name	**Avonex** Page 22	**Betaferon** Page 22	**Extavia** Page 22	**Plegridy** Page 22	**Rebif** Page 22	**Copaxone** Page 26	**Aubagio** Page 29	**Tecfidera** Page 32	**Gilenya** Page 35	**Tysabri** Page 39	**Lemtrada** Page 42
Chemical name	interferon beta 1a	interferon beta 1b	interferon beta 1b	peginterferon beta 1a	interferon beta 1a	glatiramer acetate	teriflunomide	dimethyl fumarate	fingolimod	natalizumab	alemtuzumab
How do I take the drug?	 Once a week	 Every other day	 Every other day	 Once a fortnight	 Three times a week	 Every day or three times a week	 Once daily	 Twice daily	 Once daily	 Once monthly in hospital clinic	 Two treatment courses 12 months apart
Type of MS	Active RRMS CIS	Active RRMS CIS	Active RRMS CIS	Active RRMS	Active RRMS CIS	Active RRMS CIS	Active RRMS	Active RRMS	Very active RRMS	Very active RRMS	Active RRMS Very active RRMS
How effective?	Moderately effective	Moderately effective	Moderately effective	Moderately effective	Moderately effective	Moderately effective	Moderately effective	More effective	More effective	Highly effective	Highly effective
Common side effects	• Flu-like symptoms • Injection site reactions	• Flu-like symptoms • Injection site reactions	• Flu-like symptoms • Injection site reactions	• Flu-like symptoms • Injection site reactions	• Flu-like symptoms • Injection site reactions	• Injection site reactions • Headache • Feeling sick	• Feeling sick • Diarrhoea • Hair thinning	• Flushing • Feeling sick • Diarrhoea • Stomach pains	• Increased risk of infection • Cough • Headache • Back pain • Diarrhoea	• Dizziness • Feeling sick • Itchy skin rash • Shivering • Increased risk of infection	• Infusion-related reactions • Increased risk of infection • Thyroid problems
Less common but serious side effects								• Some cases of brain infection (PML)	• Swelling in the back of eye (macular oedema) • Some cases of brain infection (PML)	• Brain infection (PML)	• Blood clotting disorder (ITP) • Kidney problems
Additional information	• Store in fridge			• Store in fridge	• Store in fridge	• Store in fridge	• Remains in the body for up to two years after stopping	• Capsule contains beef gelatin	• Capsule contains beef gelatin		

Type of MS

see page 6

Active RRMS

- if you have had two relapses in the previous two years

Very active RRMS

- highly active despite treatment - if you continue to have relapses even though you've been taking a DMD for a year

OR

- rapidly evolving severe - if you have had two or more severe, or disabling, relapses in the previous year and show areas of new damage (lesions) on two consecutive MRI scans

How effective?

see page 9

Moderately effective (category 1.1)

- reduces relapses by one third (30%)

More effective (category 1.2)

- reduces relapses by one half (50%)

Highly effective (category 2.0)

- reduces relapses by two thirds (70%)

 Injection

 Pill

 Intravenous infusion (drip)

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