



atrialfibrillationassociation

www.afa.org.uk

www.afa-international.org

ATRIAL FIBRILLATION
ACCESSING APPROPRIATE TREATMENT OPTIONS
INFORMATION PACK FOR PATIENTS

ATRIAL FIBRILLATION: ACCESSING APPROPRIATE TREATMENT OPTIONS

Information Pack for Patients

Contents:

Foreword	1
Treatment options	2
NHS Constitution	5
Appeals process	7
Useful contacts	10
Important documents	11

Foreword

The Government is embarking on an ambitious programme of reform for the NHS in England, one which is committed to shared patient decision-making – “no decision about me without me.” As an international charity which provides information, support and access to established, new or innovative treatments for Atrial Fibrillation (AF), we believe that patients are best placed to inform the care they should receive and their patient journey. We therefore fully believe that patients should have a greater say in their care and treatment options.

However, we have heard from a growing number of members about the difficulties that they are facing in accessing appropriate treatment options to manage their AF. At a time when the Government is pushing for greater patient choice and control over the management of their conditions, we believe that more needs to be done to empower patients to help achieve this goal. It is for this reason that we have produced this patient information pack which will help you, the patient or carer, to have greater control over your condition, and to help improve your quality of life.

This pack contains all the tools that you will need to help you to gain access to appropriate treatment options, and where necessary, explain how to appeal decisions which may prevent this from happening.

We would be interested in hearing from you about the struggles you have faced in accessing treatments, and where possible, help you to achieve a satisfactory outcome.

Yours sincerely,



Trudie Lobban MBE
Founder and Chief Executive

We are here to help patients with AF. Please contact AFA at:

Atrial Fibrillation Association
PO Box 1219
Chew Magna
Bristol
BS40 8WB
Tel: 01789 451 837
Info@afa.org.uk
www.afa.org.uk

Treatment Options:

What is AF?

AF is the most common heart rhythm disorder, occurring when chaotic electrical activity develops in the upper chambers of the heart – the atria. About 1-2% of the total population experience the condition; its prevalence increases with age, and over the age of 80, about 15-17% of the population is affected. Although there is a higher incidence of AF in men, women are at more risk of forming clots in the heart, and these clots can result in a stroke. AF is associated with a five-fold increased risk of thrombo-embolic strokes, and these are often severe, leading to long term disability or death. The annual cost of AF to the total NHS budget is a staggering £1.8 billion.

Unfortunately, awareness and understanding of heart rhythm disorders amongst many health professionals is low, so the patient is not currently receiving an appropriate and joined up journey of care across levels of service provision. This results in poor detection rates and sub optimal treatment for AF patients. AF is not currently prioritised despite its rising prevalence and significant contribution to stroke risk amongst patients. Furthermore, it is estimated that by 2050, 2% of the population will have AF. This is why we are working alongside patients to ensure improved prevention, diagnosis and management of the condition.

Accessing the appropriate treatment options

There is a large range of treatment options available for AF, which is continuing to grow. However, with a lack of understanding of the condition amongst some GPs, it is essential that you are aware of the various treatment options and your rights to accessing them.

Dronedaronone (Multaq)

One of the newest treatment options is Dronedaronone (Multaq), an anti-arrhythmic drug belonging to the benzofuran class of anti-arrhythmic compounds. Its main mechanism of action, like that of Amiodarone and Sotalol, is achieved through the inhibition of potassium channels making heart cells less excitable and thereby making AF less likely.

What guidance has been issued on Dronedaronone?

The National Institute for Health and Clinical Excellence (NICE) published their final Guidance on Dronedaronone (Multaq) on 25th August 2010. The Guidance states that Dronedaronone is recommended as an option for the treatment of non-permanent Atrial Fibrillation if:

- You have already tried another type of drug (usually a drug called a beta-blocker) but this has not worked, **and**
- You have at least one of the following which means you are at a higher risk of developing disease of the heart or blood vessels:
 - You are taking at least two different types of drugs for high blood pressure
 - You have diabetes
 - You have had a type of stroke or a blood clot in the past

- The left chamber of your heart is larger than normal
- Your heart is pumping less blood around your body than normal, **or**
- You are 70 or over, **and**
- You do not have a severe form of heart failure; that is, if you have been diagnosed as having heart failure, you are still able to carry out everyday tasks with either no symptoms, or symptoms that are mild (for example, you may experience mild chest pain or shortness of breath when walking or climbing the stairs).

There has recently been some publicity around the safety of Dronedarone, and in particular, a study of the drug in patients with a long-term form of AF. As a result of the findings the trial stopped. The European Medicines Agency (EMA) has recommended that the use of the drug is restricted. However, it is still recommended for maintaining heart rhythm in patients with paroxysmal or persistent AF for the maintenance of sinus rhythm after successful cardioversion.

Further details about this drug can be found at:

www.medicines.org.uk/emc/medicine/22894/SPC/Multaq+400mg+tablets/

Other anti-arrhythmic treatment options:

There are a number of other anti-arrhythmic treatment options available which might also be suitable for the treatment of your AF:

- Flecainide (www.medicines.org.uk/emc/medicine/22384/SPC/Flecainide+Acetate+50mg+Tablets/)
- Propafenone (<http://www.medicines.org.uk/EMC/medicine/10622/SPC/Arythmol++150mg+and+300mg+Tablets/>)
- Sotalol (<http://www.medicines.org.uk/emc/medicine/6451>)
- Amiodarone (www.medicines.org.uk/emc/medicine/23239/SPC/amiodarone%20100mg%20tablets/)
- Digoxin (www.medicines.org.uk/emc/medicine/23944/SPC/digoxin%20tablets%20bp%20250%20micrograms/)

How are decisions on ablations made?

Another treatment option for AF is ablation. However, ablation is not suitable or appropriate for all patients, and they are currently reserved for those with intrusive symptoms that impact significantly on quality of life, are refractory to treatment with medication or where medical therapy is contraindicated because of other conditions or intolerance.

Once you have been diagnosed with AF, you may be referred to a cardiologist who specialises in heart rhythm disorders, usually called an electrophysiologist (EP), who will be able to perform ablations. You can request a specialist referral to an electrophysiologist from either your GP or cardiologist.

The procedure of an ablation is considered a 'complex' procedure and is performed only by highly-skilled specialists. The decision as to whether a patient can undergo this treatment is largely determined by the local Primary Care Trust (PCT). However, we have heard from patient members that some PCTs have now stopped offering catheter ablation all together due to funding constraints.

Anti-coagulation

Anticoagulants are often prescribed to patients with AF to prevent blood clots from forming so easily, the most well-known being Warfarin. However, a number of new anticoagulants are now being developed. Amongst the most notable are:

Dabigatran (Boehringer-Ingelheim) - 2nd NICE Appraisal due September 2011

(<http://www.medicines.org.uk/emc/medicine/20760/SPC/>)

Rivaroxaban (Bayer HealthCare) - 1st NICE Appraisal Committee meeting due November 2011

(<http://www.medicines.org.uk/guides/rivaroxaban/Blood%20clotting/>)

Apixaban (BMS Pfizer) - Pending

(<http://www.medicines.org.uk/emc/medicine/24988/SPC/eliquis%202.5%20mg%20film-coated%20tablets/>)

Other anti-coagulation treatment options include:

- Warfarin (www.medicines.org.uk/EMC/history/21578/SPC/Warfarin+3+mg+Tablets)
- Heparin (www.medicines.org.uk/emc/medicine/8080)

NHS Constitution:

About the NHS Constitution

The NHS Constitution states: “You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.” This means that you have a right to receive an approved drug or treatment if your clinician says it is appropriate for you to receive it and it has been recommended by NICE’s technology appraisal. When a NICE technology appraisal recommends use of a drug or treatment, or other technology, the NHS must provide funding and resources for it within three months of the guidance being published. For example, the three month period for Dronedarone expired at the end of November 2010, and therefore PCTs are now expected to offer this treatment option to appropriate patients.

As a patient you also “have the right to expect local decisions on funding of other drugs and treatments to be made rationally following proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment that you and your doctor feel would be right for you, they will explain that decision to you.” Decision-making on whether to fund a treatment is left to the local PCT in order for them to provide services they feel best fit the needs of their local population. If a PCT decides that a treatment will not be funded, then it needs to be able to consider whether to fund the treatment for an individual patient on an exceptional basis.

Patient rights under the NHS Constitution:

Since January 2010, all providers and commissioners of NHS care are under a legal obligation to have regard to the NHS Constitution in all their decisions and actions. This means that the Constitution, its pledges, principles, values and responsibilities need to be fully embedded and ingrained into everything the NHS does.

With regards to treatment options, the following rights are of importance:

RIGHT

“You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.”

What this means for AF patients:

NICE health technology appraisals make recommendations on the use of specific new and existing drugs and treatments within the NHS. When a NICE technology appraisal recommends the use of a drug or treatment, PCTs must fund that drug or treatment for patients when it is clinically needed. In practice this means that you have a right to receive that drug or treatment if your clinician says it is appropriate for you to receive it and it has been recommended by NICE’s technology appraisals.

RIGHT

“You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.”

What this means for AF patients:

The availability of some healthcare services is determined nationally, for example, under NICE's technology appraisals, where all PCTs have to fund the recommended drugs and treatment. However, in most cases, decision-making on whether to fund a service or treatment is left to the local PCT. This is to enable PCTs to provide services that best fit the needs of their local population. For such local decision-making, it is important that the process is rational, transparent and fair. This right ensures that there is such a process. If a PCT has decided that a treatment will not normally be funded, it needs to be able to consider whether to fund that treatment for an individual patient on an exceptional basis. The Department of Health has issued statutory Directions to PCTs and guidance (Supporting rational local decision-making about medicines (and treatment) 2009) to ensure that their responsibilities in this area are clear.

PLEDGE

“The NHS commits to offer you easily accessible, reliable and relevant information to enable you to participate fully in your own healthcare decisions and to support you in making choices. This will include information on the quality of clinical services where there is robust and accurate information available.”

What this means for AF patients:

Providing information to support choice is a major priority for the NHS. Important developments include:

- **NHS Choices (www.nhs.uk)**, a website setting out information on services, treatments and lifestyles. It helps patients to understand what services are available and where these services can be accessed. Increasingly, the information will become available through other channels (such as mobile phones and touch-screen kiosks) which are being developed for those who do not use the internet. NHS Choices is regularly updated with new comparative information, and there is a process to ensure that this is sufficiently robust to be of real use to patients.
- **Information prescriptions**, which are available on NHS Choices and locally from healthcare professionals, help people to access relevant, reliable and personalised information about their long-term condition and how to manage their care.
- **Your health, your way – your guide to long-term conditions and self care**, which has been published on NHS Choices to provide patients with long-term conditions, such as asthma and diabetes, with information about the choices that should be available to them locally to enable them to care for themselves (self-care) in partnership with health and social care professionals.

Appeals Process:

What happens if you have been told by your Primary Care Trust (PCT) that you are unable to access an appropriate treatment?

If you have been told by your GP that you could benefit from a particular drug or treatment option, yet your local Primary Care Trust refuses this treatment option on the grounds of the cost, you may be able to apply for an individual funding request.

What is an individual funding request?

Each PCT makes a decision on how healthcare is provided to local people, including new drugs, treatments and technologies that are available on the NHS. PCTs are not legally obliged to provide every treatment that a patient requests, and as a result they prioritise treatments based on the resources that are available and the demand placed upon them.

An individual funding request is a request to a PCT for them to fund a treatment option for a patient which is out of the range of treatments that the PCT has agreed to commission. It is important to note that the process for individual funding requests may vary between PCTs, and it is therefore recommended that you get further information from your local PCT website or from the Patient and Liaison Service (PALS).

Who can apply?

This request can only be made if your GP or clinician feels that there are exceptional circumstances that must be considered for a drug or treatment to be provided. The request must be made directly by the clinician who is treating you as it is their responsibility to demonstrate that you have exceptional circumstances.

What does your GP/clinician need to do?

Your clinician will be in a position to know what your PCT requires in your individual funding request. However, information which the PCT may require includes your medical history, with information on alternative treatments which you have already received; the envisaged benefits of the favoured treatment option; the reasons behind the individual funding request; and possible implications if your treatment option is refused.

Your clinician will know what information the PCT requires when assessing your case and they will therefore work with you throughout the individual funding request application to build up your case.

The process:

Your clinician will submit your application to the committee in charge of making the decisions on individual funding requests, and the panel will consider whether to recommend to the PCT that they fund your requested treatment option.

What can patients do to appeal if an individual funding request is unsuccessful?

If your individual funding request is refused then you may be able to appeal the decision. The first thing you will need to do is to establish the grounds under which the PCT will allow you to appeal and who is on the appeal panel. You should also find out the grounds on which your case was rejected; your PCT should provide this to you, however, if it does not then you can request them under the Freedom of Information Act 2000. It is important to note, however, that the appeals panel will look at whether or not the original application was considered fairly and not whether the decision was correct or not.

Identifying your local PCT representative, healthcare and local MP:

If you have been refused a suitable treatment option and are appealing the decision, it might be worth sending a copy of your appeal to your local PCT representative, GP or clinician and your local MP.

If you are unsure of who to contact in your local PCT, then ask your GP or surgery administrative staff. They should be able to tell you who the lead person is for AF services in your area. However, if they are unable to identify a suitable person then it may be worth sending your correspondence to either the Chief Executive or the Public Health Director.

Your local MP may be able to help with your case and you may therefore wish to meet with them in person at one of their surgeries, or alternatively you can write to them to inform them of your case. To find out who your local MP is call the House of Commons Information Service on 0207 219 4272, or alternatively search online at <http://www.findyourmp.parliament.uk>. If you already know who your MP is, then you can write to them at House of Commons, London, SW1A 0AA.

When writing to your MP, you should set out your case, providing them with a background of your condition and the problems that you have experienced in accessing appropriate treatment options. You may also wish to ask them to support your case by writing to the PCT.

Throughout the process, it is worth sending a copy of the correspondence to your GP and/or clinician as a courtesy, as they may be able to discuss the appeal in greater detail.

Template letters to send to your local PCT and MP can be found in the Resources Pack.

How to get the campaign in your local media:

If you feel that your case is not being heard properly then it may be worth considering contacting your local media to generate attention to your case, and place greater pressure on the PCT. However, this should only be done if you feel comfortable with your case being in the public domain and you are willing and able to share your story with journalists and the public. For some, the media can be daunting and you must therefore be certain that you will be comfortable speaking to journalists on the phone, being quoted in the press and on occasions, speaking on the radio or being filmed.

If this is an element to your campaign that you would like to explore then you should get in contact with your local media, whether this is the press, radio or TV. To establish the name of the relevant journalist or researcher you should phone the organisation and get a name. You can then contact them either by email, letter, or phone if you are confident doing this. However, it is worth remembering that there is no guarantee that your story will be published/filmed as journalists receive lots of stories each day, and you should therefore not be discouraged.

Before contacting the media to highlight your case it is important that you have given your local PCT enough time to respond as matter of courtesy.

If you would like advice or information about the condition then please contact AFA on 01789 451837 or info@afa.org.uk.

What is the complaints process?

If you are still unhappy with the way your case was handled, you can use the NHS Complaints process. The NHS Complaints process has three stages:

Stage 1: Acknowledge your complaint

Stage 2: Investigating your complaint

Stage 3: Responding to your complaint

Please note that this complaints process can be long and it will not result in your preferred treatment option being funded.

Once you have been through this complaints process, if you are still unhappy then you can refer the matter to the Parliamentary and Health Service Ombudsman.

Useful Contacts:

Atrial Fibrillation Association (AFA):

www.afa.org.uk

AFA
PO Box 1219
Chew Magna
Bristol
BS40 8WB
01789 451 837

Patient Advice and Liaison Service (PALS):

www.pals.nhs.uk

Parliamentary and Health Service Ombudsman:

www.ombudsman.org.uk

The Parliamentary and Health Service Ombudsman
Millbank Tower
Millbank
London
SW1P 4QP
0345 015 4033

Citizens Advice:

www.citizensadvice.org.uk

0844 477 2020

MP Finder:

www.findyourmp.parliament.uk

020 7219 4272

Arrhythmia Alliance

The Heart Rhythm Charity

www.heartrhythmcharity.org.uk

Important Documents:

NHS Constitution:

www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx

Funding of technology appraisal guidance from the National Institute for Health and Clinical Excellence (NICE):

www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Directionsfromthesecretaryofstate/DH_4075685

List of PCTs in England:

www.nhs.uk/ServiceDirectories/Pages/PrimaryCareTrustListing.aspx

NICE Patient Guide for Dronedarone:

www.guidance.nice.org.uk/TA197

NICE Appraisal of Dabigatran:

www.guidance.nice.org.uk/TA/Wave21/10

NICE Appraisal of Rivaroxaban:

www.guidance.nice.org.uk/TA/Wave24/18

