

Atrial fibrillation

Accessing appropriate treatment options



Providing information, support and access to established,
new or innovative treatments for atrial fibrillation

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Foreword

The Government is embarking on an ambitious programme of reform for the NHS in England, one of 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 choose 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 patients 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 report which will help you, the patient or carer, to have greater control over your condition and to help improve your quality of life.

This report contains all the tools that you will need to help you to gain access to appropriate treatment options and, where necessary, explains 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. Similarly, feedback of positive experiences would be welcomed, as this information may encourage and empower other patients to achieve similar outcomes.



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What is AF?

AF is the most common heart rhythm disorder in the UK, occurring when chaotic electrical activity develops in the upper chambers of the heart - the atria.

About 1-2% of the total UK population have the condition; its prevalence increases with age, and over the age of 80, about 15-17% of the population are 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 an AF-related stroke.

There are an estimated 150,000 strokes in the UK each year, and 1 in 5 of these strokes (30,000), are due to AF.

AF is associated with a five-fold increased risk of thromboembolic strokes: 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 some health professionals is low, so many patients are 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 the AF Association is working alongside patients to ensure improved prevention, diagnosis and management of the condition.

NHS Constitution

About the NHS Constitution

The NHS Constitution states: “You have the right to drugs and treatments that have been recommended by the National Institute for Health and Care Excellence (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 (with your medical history) and it has been recommended by NICE’s technology appraisal. When a NICE technology appraisal recommends use of a drug, treatment or other technology, the NHS must provide funding and resources for it within three months of the guidance being published.

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 Clinical Commissioning Group (CCG) in order for them to provide services they feel best fit the needs of their local population. If a CCG 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 pay careful attention 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.

YOUR 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, CCGs 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.

YOUR 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 that 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 are determined nationally, for example, under NICE's technology appraisals, where all CCGs 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 CCG. This is to enable CCGs 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 CCG 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 CCGs and guidance (supporting rational local decision-making about medicines and treatment) to ensure that their responsibilities in this area are clear.

NHS 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, 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 in partnership with health and social care professionals.



Accessing the appropriate treatment options

There is a wide range of treatment options available for AF, and this 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.

Anticoagulation

Anticoagulants are prescribed to patients with AF to prevent AF-related stroke. In Britain, they currently include warfarin, dabigatran, rivaroxaban, apixaban, edoxaban and heparin.

The NICE guideline of 2014 recommends that all people with AF, except those with no stroke risk factors (see below), should be offered anticoagulation therapy to reduce this risk of stroke.

CHA ₂ DS ₂ -VASc scoring criteria to determine need for blood thinning based on AF-related stroke risk													
Congestive heart disease	1 point	<table border="1"><thead><tr><th>score</th><th>risk level</th><th>necessity for anticoagulant</th></tr></thead><tbody><tr><td>0</td><td>low risk</td><td>anticoagulant not suggested</td></tr><tr><td>1</td><td>at risk</td><td rowspan="2">anticoagulant suggested dependent on personal preferences</td></tr><tr><td>2+</td><td>at risk</td></tr></tbody></table>	score	risk level	necessity for anticoagulant	0	low risk	anticoagulant not suggested	1	at risk	anticoagulant suggested dependent on personal preferences	2+	at risk
score	risk level		necessity for anticoagulant										
0	low risk		anticoagulant not suggested										
1	at risk		anticoagulant suggested dependent on personal preferences										
2+	at risk												
Hypertension	1 point												
Age (75 years +)	2 points												
Diabetes	1 point												
Stroke or previous TIA	2 points												
Vascular heart disease	1 point												
Age (65-74 yrs)	1 point												
Sex (female)	1 point												
SCORE	<input type="text"/>												

AF Association has a range of information factsheets on all of the anticoagulants. The NICE guideline of 2014 recommends that all people with AF, except those with no stroke risk factors (see below), should be offered anticoagulation therapy to reduce this risk of stroke.

Please visit www.afa.org.uk where you can view, download and print all of our patient resources or call +44 (0)1789 867 502.

Accessing an appropriate anticoagulant

NICE guidance on the use of anticoagulants in AF was updated in June 2014. As part of this guidance, CCGs are expected to offer all anticoagulants as options for appropriate patients. A person who has AF and has been assessed as requiring anticoagulation therapy can request a specific option based on safety, effectiveness and lifestyle need, provided it is appropriate for their medical needs. It should be routine good clinical practice that any patient being prescribed anticoagulation is also assessed for excess risk of bleeding as well as AF-related stroke risk to ensure appropriate monitoring and prescribing.

In this 2014 update, aspirin on its own was no longer recommended as a suitable therapy for AF-related stroke risk reduction.

Left atrial appendage occlusion

This procedure involves closing the muscular pouch on the heart known as the left atrial appendage. In AF, blood clots may form in this pouch, travel up to the brain and block an artery, causing an AF-related stroke. In order to prevent blood clots from doing this, the pouch is closed off (occluded) by placing a device over its entrance to the heart.

Closure of the left atrial appendage may be suitable for those patients who require protection from AF-related stroke but who cannot tolerate anticoagulation for medical reasons. Not all patients are suitable for this procedure, but they can discuss their eligibility with an electrophysiologist.

Antiarrhythmic medications

Dronedarone

Dronedarone (marketed as 'Multaq') is an antiarrhythmic drug belonging to the benzofuran class of antiarrhythmic 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 dronedarone?

NICE published their final guidance on dronedarone in August 2010. The guidance states that dronedarone is recommended as an option for the treatment of non-permanent atrial fibrillation if you have already tried another type of drug (usually 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 heart disease:

- 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
- You are 70 years old or over
- 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 been 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. Dronedarone is only suitable for certain patients diagnosed with AF and consideration for its use needs to be made by a heart rhythm specialist with access and knowledge to the patient's full medical history.

Other antiarrhythmic treatment options:

There are other antiarrhythmic treatment options available which might also be suitable for the treatment of your AF. These are divided in different classes of antiarrhythmics, and some of them have very particular applications:

Amiodarone
Diltiazem
Propranolol

Bisoprolol
Flecainide
Sotalol

Digoxin
Propafenone
Verapamil

Cardiac ablation

Another treatment option for AF is cardiac ablation, and there are several kinds involving varying degrees of invasiveness. The ablation procedure involves destroying the area of the heart tissue through which the irregular electrical impulses pass, thereby preventing them from causing the fibrillation.

Once you have been diagnosed with AF, you may be referred to a cardiologist who specialises in heart rhythm disorders, 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.

How are decisions on ablation made?

Ablation is not suitable or appropriate for all patients, and the procedure is 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.

The ablation procedure is a complex procedure and is performed only by highly skilled specialists. Catheter ablation for AF is funded by NHS England Specialist Commissioners and so it may be necessary that you seek a referral to a Consultant Cardiologist who is also an Electrophysiologist (EP) for review and consideration for this treatment option. An extensive list of EPs and specialist arrhythmia healthcare professionals is available on the Heart Rhythm Specialist website, www.heartrhythmspecialists.org. A referral to a specialist can be sought from your GP or current healthcare professional.

Appeals process

What happens if you have been told by your CCG 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 CCG 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 CCG makes a decision on how healthcare is provided to local people, including new drugs, treatments and technologies that are available on the NHS. CCGs 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 CCG for them to fund a specific treatment option for a patient which is out of the range of treatments that the CCG has agreed to commission. It is important to note that the process for individual funding requests may vary between CCGs, and it is therefore recommended that you get further information from your local CCG website or from the Patient and Liaison Service (PALS) at your local hospital.

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 CCG requires in your individual funding request. However, information that the CCG 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 CCG requires when assessing your case and they will therefore work with you throughout the individual funding request application to build 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 CCG 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 CCG 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 CCG 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 CCG 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 CCG representative, GP or clinician, and your local MP.

If you are unsure who to contact in your local CCG, 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.

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 Enquiry Service on +44 (0) 207 219 4272, or alternatively search online at <http://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 CCG.

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.

Donation Form



Your details

Title _____ First Name(s) _____ Surname _____
Address _____
Postcode _____
Email _____ Phone number _____

Your donation Please tick method of payment & complete relevant section:

enclose a cheque made payable to 'AF Association' for £ _____

or Please debit my credit/debit card for £ _____ Card type maestro visa mastercard
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*I am a UK taxpayer and understand that if I pay less Income Tax and/or Capital Gains Tax than the amount of Gift Aid claimed on all my donations in that tax year it is my responsibility to pay any difference. Please notify us if you want to cancel this declaration, change your name or home address or no longer pay sufficient tax on your income and/or capital gains. Your address is needed to identify you as a current UK taxpayer.

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Post me to: AF Association, Unit 6B, Essex House, Cromwell Business Park, Chipping Norton, OX7 5SR

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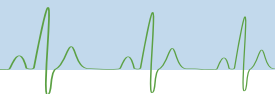
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Please remember that this publication provides general guidelines only. Individuals should always discuss their condition with a healthcare professional.

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