

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology guidance scope

### Alpha-Stim AID for anxiety disorders

#### 1 Technology

##### 1.1 *Description of the technology*

Alpha-Stim AID (Electromedical Products International, Inc) is an electrotherapy device for managing anxiety, insomnia and depression. This scope focuses on the use of Alpha-Stim AID for anxiety disorders. The technology was developed in 1981 in the US, and Alpha-Stim AID is the latest model.

Alpha-Stim AID uses cranial electrotherapy stimulation (CES), by providing a variable electrical microcurrent to the brain which stimulates alpha wave electrical activity. The current has a pulse repetition rate of 0.5 hertz and is composed of bipolar asymmetric rectangular waves in a cycle that repeat periodically at 10 second intervals.

Alpha-Stim AID is the size of a mobile phone and has a pair of small clips with removable soft pads that need to be moistened with a solution which conducts electricity. The current is applied by these clips that attach to the ear lobes and the strength of the current can be adjusted. Alpha-Stim AID is recommended to be used for between 20 and 60 minutes every day, every other day, or on an as-needed basis. Alpha-Stim AID is battery powered, which allows users to be mobile when using it.

Alpha-Stim AID is not suitable for people with cardiac pacemakers and implanted defibrillators. The technology may be suitable for use during pregnancy. Children should use Alpha-Stim AID under adult supervision.

## **1.2      *Relevant diseases and conditions***

Anxiety disorders are common mental health conditions and include generalised anxiety disorder, social anxiety disorder, post-traumatic stress disorder (PTSD), panic disorder, obsessive–compulsive disorder and body dysmorphic disorder. There is considerable variation in the severity of anxiety disorders, and some are associated with significant long-term disability. They can be distressing for the person affected, their families, friends and carers, and can have an impact on their local communities. Anxiety disorders can have a lifelong course of relapse and remission.

In the UK in 2010, 8.2 million adults were diagnosed with an anxiety disorder and the cost of treatment for the anxiety disorder was estimated to be £11,687 for each adult, and it is one of the most costly psychiatric and neurological disorders ([Fineberg et al. 2013](#)). An adult psychiatric morbidity survey in England reported that the 1-week prevalence of generalised anxiety disorder was 6.6% and anxiety disorders were more common in women than in men, with the most apparent difference in those aged between 16 and 24 (respectively GAD 9.0%; phobias 5.4%; OCD 2.4%; and panic disorder 2.2%) than in other age sex groups ([McManus et al. 2014](#)).

## **1.3      *Current management***

NICE's guideline on [generalised anxiety disorder and panic disorder in adults](#) provides principles of care for people with generalised anxiety disorder (GAD). It also recommends a stepped-care model to organise service provision and to help people with GAD, their families, carers and practitioners to choose the most effective intervention.

NICE's guideline on [social anxiety disorder: recognition, assessment and treatment](#) provides treatment principles for treating adults with social anxiety disorder. It recommends that individual cognitive behavioural therapy (CBT) that has been specifically developed should be offered to adults with social anxiety disorder. If the person wishes to proceed with a pharmacological intervention, a selective serotonin reuptake inhibitor (SSRI) (escitalopram or sertraline) should be offered. For adults who decline cognitive behavioural and

pharmacological interventions, short-term psychodynamic psychotherapy that has been specifically developed to treat social anxiety disorder should be considered. The guideline also provides recommendations on interventions for children and young people with social anxiety disorder. Pharmacological interventions should not be offered to treat social anxiety disorder in children and young people.

NICE's guideline on [post-traumatic stress disorder \(PTSD\)](#) provides recommendations on management of PTSD including active monitoring, psychological-focused debriefing, psychological interventions and drug treatment. Drug treatments are not recommended for the prevention or treatment of PTSD.

NICE's guideline on [common mental health problems: identification and pathways to care](#) describes a stepped-care model for organising the provision of services and helping people with common mental health disorders, their families and healthcare professionals to choose the most effective interventions. Common mental health problems included in this guideline are: general anxiety disorder, depression, panic disorder, obsessive compulsive disorder and post-traumatic stress disorder.

## **1.4 Regulatory status**

Alpha-Stim AID was CE marked as a class IIa medical device in 2012.

A search of the Medicines and Healthcare products Regulatory Agency website shows no manufacturer field safety notices or medical device alerts for the technology.

### ***Claimed benefits***

The benefits to people with anxiety disorders claimed by the company are:

- Improvement in anxiety and depression symptoms
- Increased treatment choices for people with anxiety disorders
- An alternative management to pharmacological and/or psychological interventions which do not always work or are not desired by everyone with anxiety disorders

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- Additional benefit when combined with psychological interventions
- An alternative option to be used in people with medical co-morbidity and disability who might not be able to travel to appointments or tolerate medication
- Home use for the potential reduction in time and cost associated with attending appointments

The benefits to the healthcare system claimed by the company are:

- Reduced cost when comparing with intensive psychological treatment such as individual CBT (iCBT)
- Reduced use of healthcare resources; for instance reducing GP visits or outpatient visits
- Reduced cost in treating complications of medication use such as overdose

## 2 Decision problem

Population	People with anxiety disorders
Intervention	Alpha-Stim AID as a stand-alone intervention or as an additional treatment to psychological interventions
Comparator(s)	<ul style="list-style-type: none"> <li>• Pharmacological interventions (e.g. selective serotonin reuptake inhibitors)</li> <li>• Psychological interventions (e.g. self-help, group or individual CBT)</li> </ul>
Outcomes	<p>The outcome measures to consider include:</p> <ul style="list-style-type: none"> <li>• Anxiety and depression symptoms scores</li> <li>• Use of psychological interventions</li> <li>• Use of pharmacological interventions</li> <li>• Number of GP visits</li> <li>• Waiting time for psychological treatments</li> <li>• Pharmacological related adverse events such as overdose</li> <li>• Patient quality of life measures</li> <li>• Treatment compliance</li> <li>• Device related adverse events</li> </ul>
Cost analysis	<p>Costs will be considered from an NHS and personal social services perspective.</p> <p>The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared.</p> <p>Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.</p>

Subgroups to be considered	<ul style="list-style-type: none"> <li>• People who also have other mental health disorders such as depression</li> <li>• People with other comorbidities (i.e. chronic physical conditions such as diabetes or cardiovascular disease)</li> <li>• Severity of anxiety (e.g. anxiety disorder assessment)</li> </ul>	
Special considerations, including those related to equality	The condition can have a significant effect on individuals' daily lives. This may mean someone is disabled if their anxiety disorder has a substantial and long-term effect on their ability to do daily activities. Disability is a protected characteristic under the Equality Act. People from certain socially excluded groups that would benefit from psychological interventions might be less likely to access them, such as black and minority ethnic groups; older people; those in prison or in contact with the criminal justice system; and ex-service personnel. Young women are more likely to have anxiety disorder. Sex and age are all protected characteristics under the Equality Act 2010	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	No	

### 3 Related NICE guidance

#### Published

- [Anxiety disorder](#) (2014) NICE quality standard [QS53].
- [Common mental health problems: identification and pathways to care](#) (2011). NICE guideline [CG 123].
- [Generalise anxiety disorder and panic disorder in adults](#) (2019) NICE guideline [CG113].
- [Obsessive-compulsive disorder and body dysmorphic disorder](#) (2005) NICE guideline [CG31].
- [Post-traumatic stress disorder](#) (2018) NICE guideline [NG 116].

[Social anxiety disorder: recognition, assessment and treatment](#) (2013).

NICE guidance [CG159].

## **4 External organisations**

### **4.1 Professional**

The following organisations have been asked to comment on the draft scope:

- Association of British Neurologists
- Association of Neuroscience Nurses
- Brain Research UK
- British Association for Counselling and Psychotherapy
- British Association of psychotherapists
- British Pain Society
- British Psychological Society
- British Psychotherapy Foundation
- College of Mental Health Pharmacy
- Counsellors and Psychotherapists in Primary Care
- Institute of Neurology
- Primary Care Mental Health Education
- Primary Care Neurology Society
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Nursing

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- Royal College of Physicians
- Royal College of psychiatrists
- Society of British Neurological Surgeons
- The Association of Neurophysiological Scientists
- United Kingdom Council for Psychotherapy

## **4.2 Patient**

NICE's [Public Involvement Programme](#) suggested the following organisations for patient commentary on the use of Alpha-Stim AID during the guidance development::

- Anxiety alliance
- Anxiety UK
- Aware defeat depression
- Big white wall
- Depression UK
- Hope2Sleep
- Maternal OCD
- Mind
- Mental health alliance
- Mental health foundation
- Mental health for self help and the big life group
- No panic
- Norther Ireland agoraphobia and anxiety society (NIAAS)

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- OCD-UK
- OCD action
- PADNAS foundation
- Social anxiety UK (SA-UK)
- The sleep council
- Triumph over phobia