

Focused Ultrasound Reimbursement in the United Kingdom

In the UK the National Health Service (NHS) is the public, tax funded healthcare system providing free service to every citizen. The National Institute for Health and Care Excellence (NICE) provides Health Technology Assessments for new clinical procedures, which are used as guidance for reimbursement by the NHS. However, a positive NICE guidance does not automatically result in NHS coverage. Below is an overview of NICE guidance in the three dimensions of Safety, Efficacy and Use and available NHS coverage for FUS procedures where such data are available. More details with respective ICD-10 diagnosis and OPCS procedure codes are collected further below. With no agreed NHS access except for prostate cancer and Essential tremor from April 2021 onwards, FUS treatments in the UK are limited to either private out-of-pocket pay or grant funded research.

Indication / FUS Procedure	NICE Safety	NICE Efficacy	NICE Use	NHS coverage
Essential Tremor	GREEN	YELLOW	GREEN	GREEN
Parkinson's Tremor	RED	RED	YELLOW	RED
Neuropathic Pain	RED	RED	RED	RED
Glaucoma	RED	RED	YELLOW	RED
Prostate Cancer	GREEN	YELLOW	GREEN	GREEN
Uterine Fibroids – US guided	YELLOW	YELLOW	GREEN	YELLOW
Uterine Fibroids – MRI guided*	GREEN	GREEN	GREEN	RED
Breast Fibroadenoma	GREEN	RED	GREEN	RED
Thyroid Nodules	GREEN	YELLOW	GREEN	RED

Overview NICE guidance and NHS coverage: **YELLOW** for Safety means well known risks for complications the user needs mitigate. **YELLOW** for Efficacy typically means evidence is limited in quantity, **RED** means inadequate quality and quantity. **GREEN** for Use includes special arrangements for clinical governance, consent, and audit, which is not a major limitation. **YELLOW** means research only and **RED** a categorical not to use. **YELLOW** for NHS coverage means in discussion, no decision yet.

* Efficacy considered adequate short term, further treatment may be required long term

Essential Tremor		
NICE procedure definition	Unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor	
NICE guideline, year	www.nice.org.uk/guidance/ipg617	June 2018
NICE recommendation	The evidence on the safety of unilateral MRI-guided focused ultrasound thalamotomy for treatment-resistant essential tremor raises no major safety concerns . However, current evidence on its efficacy is limited in quantity . Therefore, this procedure should not be used unless there are special arrangements for clinical governance, consent, and audit or research.	
Clinical Classification	ICD-10	G25.0 Essential tremor

	OPCS-4	A03.2 Stereotactic ablation of tissue of thalamus Y11.5 Ultrasonic destruction of organ NOC Y53.7 Approach to organ under magnetic resonance imaging control
NHS commissioning	https://www.england.nhs.uk/publication/transcranial-magnetic-resonance-guided-focused-ultrasound-thalamotomy-for-treatment-of-medication-refractory-essential-tremor/	
NHS coverage	<p>Limited to patients who no longer respond (adequately) to medication and are not suitable for DBS.</p> <p>Only 40-50 DBS procedures are performed in England per year and 150 treatments are allocated to tCMRgFUS per year, subject to future review.</p> <p>Coding and reimbursement is via established codes, see above</p> <p>Average payment of £ 7,083</p>	

Prostate Cancer		
NICE procedure definition	Focal therapy using high-intensity focused ultrasound for localised prostate cancer	
NICE guideline, year	www.nice.org.uk/guidance/ipg424	April 2012
NICE recommendation	<p>Current evidence on focal therapy using high-intensity focused ultrasound (HIFU) for localised prostate cancer raises no major safety concerns. However, evidence on efficacy is limited in quantity and there is a concern that prostate cancer is commonly multifocal. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</p>	
Clinical Classification	ICD-10	C61.X Malignant neoplasm of prostate
	OPCS-4	M71.1 High intensity focused ultrasound of prostate Y53.2 Approach to organ under ultrasonic control And/or Y53.7 Approach to organ under magnetic resonance imaging control
NHS coverage	<p>£1 800</p> <p>Prerequisite for HIFU therapy is using mpMRI and transperineal biopsy for diagnosis, which are reimbursed separately.</p>	

Tremor in Parkinson's Disease		
NICE procedure definition	Unilateral MRI-guided focused ultrasound thalamotomy for moderate to severe tremor in Parkinson's disease	
NICE guideline, year	www.nice.org.uk/guidance/ipg606	Feb. 2018
NICE recommendation	<p>Current evidence on the safety and efficacy of unilateral MRI-guided focused ultrasound thalamotomy for moderate to severe tremor in Parkinson's disease is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research.</p>	
Clinical Classification	ICD-10	G20 Parkinson's disease
	OPCS-4	A03.2 Stereotactic ablation of tissue of thalamus Y11.5 Ultrasonic destruction of organ NOC

		Y53.7 Approach to organ under magnetic resonance imaging control
NHS coverage	no	

Neuropathic Pain		
NICE procedure definition	Transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain	
NICE guideline, year	www.nice.org.uk/guidance/ipg632	Nov 2018
NICE recommendation	Current evidence on the safety of transcranial MRI-guided focused ultrasound thalamotomy for neuropathic pain shows there are serious safety concerns . There is very limited evidence of efficacy. Therefore, this procedure should not be used .	
Clinical Classification	ICD-10	M79.2 Neuralgia and neuritis, unspecified
	OPCS-4	A03.2 Stereotactic ablation of tissue of thalamus Y11.5 Ultrasonic destruction of organ NOC Y53.7 Approach to organ under magnetic resonance imaging control
NHS coverage	no	

Glaucoma		
NICE procedure definition	High-intensity focused ultrasound for glaucoma	
NICE guideline, year	https://www.nice.org.uk/guidance/ipg661	Sep 2019
NICE recommendation	Evidence on the safety and efficacy of high-intensity focused ultrasound for glaucoma is inadequate in quantity and quality . Therefore, this procedure should only be used in the context of research .	
Clinical Classification	ICD-10	H40.- Glaucoma
	OPCS-4	C66.5 Destruction of ciliary body NEC Y13.5 Ultrasonic destruction of lesion of organ NOC
NHS coverage	no	

Uterine Fibroids – Ultrasound guided		
NICE procedure definition	Ultrasound-guided high-intensity transcatheter focused ultrasound for symptomatic uterine fibroids	
NICE guideline, year	www.nice.org.uk/guidance/ipg657	July 2019
NICE recommendation	Current evidence on the safety of ultrasound-guided high-intensity transcatheter focused ultrasound for symptomatic uterine fibroids shows there are well-recognised complications including skin burns . The evidence on efficacy is limited in quality . Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.	
Clinical Classification	ICD-10	D25.- Leiomyoma of uterus
	OPCS-4	Q20.6 Focused ultrasound to lesion of uterus Y53.2 Approach to organ under ultrasonic control
NHS coverage	In discussion, no decision yet	

Uterine Fibroids – MRI guided		
NICE procedure definition	Magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids	
NICE guideline, year	www.nice.org.uk/guidance/ipg413	Nov 2011
NICE recommendation	Current evidence on the efficacy of magnetic resonance image (MRI)-guided transcutaneous focused ultrasound for uterine fibroids in the short term is adequate , although further treatment may be required and the effect on subsequent pregnancy is uncertain . There are well-recognised complications but the evidence on safety is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit .	
Clinical Classification	ICD-10	D25.- Leiomyoma of uterus
	OPCS-4	Q20.6 Focused ultrasound to lesion of uterus Y53.7 Approach to organ under magnetic resonance imaging control
NHS coverage	no	

Breast Fibroadenoma		
NICE procedure definition	High-intensity focused ultrasound for symptomatic breast fibroadenoma	
NICE guideline, year	www.nice.org.uk/guidance/ipg592	Sep 2017
NICE recommendation	The evidence on high-intensity focused ultrasound for symptomatic breast fibroadenoma raises no major safety concerns . Evidence on its efficacy is inadequate in quantity and quality . Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.	
Clinical Classification	ICD-10	D24.X Benign neoplasm of breast
	OPCS-4	B40.8 Other specified destruction of lesion of breast Y13.5 Ultrasonic destruction of lesion of organ NOC
NHS coverage	no	

Thyroid Nodules		
NICE procedure definition	High-intensity focused ultrasound for symptomatic benign thyroid nodules	
NICE guideline, year	www.nice.org.uk/guidance/ipg643	Feb 2019
NICE recommendation	The evidence on the safety of high-intensity focused ultrasound for symptomatic benign thyroid nodules raises no major safety concerns , however the current evidence on its efficacy is limited in quantity and quality . Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.	
Clinical Classification	ICD-10	E04.1 Nontoxic single thyroid nodule - Or - E05.1 Thyrotoxicosis with toxic single thyroid nodule
	OPCS-4	B12.8 Other specified operations on thyroid gland Y13.5 Ultrasonic destruction of lesion of organ NOC Y53.- Approach to organ under image control
NHS coverage	no	

This summary was compiled by [Thomas Andreae, PhD](#), the Focused Ultrasound Foundation's Ambassador in Europe. Please contact him for more information.