National Institute for Health and Care Excellence

IP1730 MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy

IPAC date: 12/12/19

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1**	I am a consultant Neurosurgeon with a specific interest in Epilepsy Surgery. I see the laser ablation as a tool that should be used in highly specialised epilepsy centres where there is an appropriate MDT discussion with regards to possible treatment options for patients. The laser should be an available treatment option for patients with hypothalamic hamartomas where resective or disconnection surgery is high risk and gamma knife is only partially effective. Deeply located lesions could benefit from laser ablation avoiding the invasiveness of open surgery. With an appropriate indication and in highly specialised centres this will be an invaluable tool to treat more patients affected by drug resistance epilepsy.	Thank you for your comments. Section 1.3 in the guidance states that **'**Patient selection should be done by a multidisciplinary team experienced in managing drug-resistant epilepsy. This may include a neurologist, neurosurgeon, neurophysiologist, neuroradiologist and psychiatrist'. IPAC considered you comment and added to the guidance in section 1.4 that ***'****The procedure should only be done in specialised epilepsy centres by clinicians with experience and specific training'.* This guidance is for all types of drug resistant epilepsy and not focused on any specific types of epilepsy. The overview of evidence was mainly related to temporal lobe epilepsy (Grewal 2019, Xue 2018) and hypothalamic hamartomas in paediatric patients (Hoppe 2017). IPAC considered your comment in relation to hypothalamic hamartomas and amended Section 3.5 as follows: *'The committee noted that, in adults, the procedure has primarily been used to treat temporal lobe*

				epilepsy and in children for hypothalamic hamartomas'.
2	Consultee 2 NHS Professional	**1, General**	MRI guided laser interstitial thermal therapy (MRIgLITT) has gained rapid acceptance amongst colleagues in the USA who have had access to the technique for several years now; and randomised trials are under way. Advantages with rapid recovery following the procedure and quick discharge from hospital make it an attractive procedure, most commonly undertaken for medial temporal lobe epilepsy. There is some evidence that Neuropsychological deficits following MRIgLITT are smaller compared to standard anterior temporal lobectomies. It is used for lesions typically less than 2 cm in diameter. In addition to medial temporal lobe epilepsy, there are likely significant benefits for patients who have deep lesions as the cause of their epilepsy. This includes hypothalamic hamartomas and certain deep heterotopias, including periventricular heterotopias. In some cases such as deep temporooccipital heterotopic lesions the lesion could be destroyed with minimal damage of the white matter tracts (optic radiation) and avoid a hemianopia, which is an often rather devastating side effect of a resection targeting such deep lesions in that region. The data on such pathologies are still sparse, but it seems very likely that patients will very much benefit here with reduced surgical morbidity. MRIgLITT may in the future be the preferred treatment option for such patients, who currently have very high risks of surgical morbidity. It would be extremely welcome if carefully selected patients could get access to this treatment option.	Thank you for your comments and for identifying some of the advantages of the procedure. IPAC notes there are randomised trials under way. IPAC considered your comment about neuropsychological deficits may be reduced compared with other surgical intervention. IPAC also considered the comment in relation to hypothalamic hamartomas and other deeply located lesions and amended Section 3.5 as follows: *'The committee noted that, in adults, the procedure has primarily been used to treat temporal lobe epilepsy and in children for hypothalamic hamartomas'.* Section 1.3 in the guidance states **'**Patient selection should be done by a multidisciplinary team experienced in managing drug-resistant epilepsy. This may include a neurologist, neurosurgeon, neurophysiologist, neuroradiologist and psychiatrist'.
3	Consultee 3 NHS Professional	**General**	Something that needs to be emphasized is that LiTT offers the possibility of seizure freedom with a minimally invasive procedure that be done with a 1 day stay in hospital and avoids craniotomy.	Thank you for your comments. Committee discussed your views including the low invasive nature of the procedure and

			Thus, firstly, headache and fatigue are less, and patients would usually get normally get back to their usual activities in a week rather than 2-3 months. Secondly the part of the brain that is causing the epilepsy can be ablated, with avoiding removing the adjacent brain that would need to be removed to get access to the target areas with open surgery. Hence the adverse consequences on brain function are less.	the short stay in hospital and short recovery time.
4	Consultee 4 NHS Professional	**1**	I am writing to highlight the great need for this treatment modality MRI-guided laser interstitial thermal therapy (MRgLITT) to be recognised by NICE as an intervention for people living with epilepsy where drug therapies are not able to control daily seizures. Current, NICE recommendations identify people with only certain types of epilepsy to be suitable to access this treatment modality. Some heath trusts are using NICE guidance definitively as a reason not to offer this treatment to people with rare types of epilepsy despite support for these cases from Neurology Consultants and expert Professors in this field. MRgLITT is a relatively new therapy and therefore the evidence base for the effectiveness of this treatment for other types of epilepsy will be limited. However, we can learn from current practice to support this innovation safely. For some people with rare types of epilepsy this offers the only chance of a least restrictive surgical procedure which could positively change their current life circumstances. It is important that NICE widens the recommendations around the types of epilepsy that this treatment is suitable for, to enable people with rare types of epilepsy like Gelasic Epilepsy to have equal opportunity to access treatment. This action by NICE would have the impact for people in these circumstances to access this treatment and therefore provide hope if this is successful in reducing or diminishing the experience of daily seizures through the least invasive surgical procedure. Fair and equal opportunity to access	Thank you for your comments. IPAC discussed the recommendations in relation to the types of epilepsy that this treatment is suitable for. In particular its guidance in relation to rare causes, and any equalities issues. This guidance is for all types of drug resistant epilepsy and not focused on any specific types of epilepsy. The overview of evidence was mainly related to temporal lobe epilepsy (Grewal 2019, Xue 2018) and hypothalamic hamartomas in pediatric patients (Hoppe 2017). As there is uncertainty about the efficacy of this procedure, recommendations in 1.1 and 1.2 suggest that clinicians should use the procedure with special arrangements which includes informing clinical governance lead, informing patients clearly, taking consent and auditing outcomes. Section 1.5 of the draft guidance also recommends further research in the form of randomized controlled trial, large case series or collaborative registries. These recommendations allow patents to access a procedure with appropriate

			treatment should be recognised by NICE. Not only will it offer people who are experiencing this chronic condition hope for a better life, it will also support to build the evidence base for this therapy along with advancing understanding within the neurological field.	safeguards and caution. The impact on equality has been assessed during guidance development according to the principles of the NICE Equality scheme. IPAC also considered the comment in relation to hypothalamic hamartomas and other deeply located lesions and amended Section 3.5 as follows: *'The committee noted that, in adults, the procedure has primarily been used to treat temporal lobe epilepsy and in children for hypothalamic hamartomas'.*
5	Consultee 4 NHS Professional		CASE STUDY: The individual that I will discuss has Gelasic Epilepsy due to a small tumour in their hypothalamus. This person is a male aged 32. He currently lives with his parents who provide him with support, equivalent to 24hr supported living. The seizures that this individual experience happen around 8 to 10 time a day. They leave the individual exhausted and disoriented to task and place. Following and during a seizure the person needs support to manage any risks and then reorient him back to the task at hand. The individual experiences sleep difficulties as his seizures are particularly bad at night times. The person has future goals that he would like to achieve, they include being able to gain permanent employment. He has been unable to do this due to the nature of his fits. Not having a productive role and being able to live a normal life has led to the individual experiencing severe anxiety and depressive episodes. The prolonged damage and side effects of the drugs and seizures continues to impact on the individual's cognitive and social functioning. Over the years it has been noted that the individual's abilities have declined, and this is the expected prognosis. Through the years many different drug therapies have been tried some with more success than others. However, the individual has never been fit free and the drug success has been about the effect they have on	Thank you for your comments and bringing to the committee's attention this UK case study. Committee discussed the clinical implications (in terms of efficacy and safety of the procedure) of this case study, and your views in their deliberations. It is not within the remit of the IP programme to evaluate the cost effectiveness of interventional procedures, or to advise the NHS on whether interventional procedures should be funded and available in the NHS. IPAC discussed your suggestion to revise the guidance to make recommendations for people for whom drug therapies are not effective in controlling daily seizures. IPAC specifies that the recommendations in the guidance are for all types of drug resistant epilepsies and not focused on /or restricted for any specific types of epilepsy.

			the severity of the fit. The drugs regimes are becoming increasingly less effective. The last option now available for a better quality of life and hope for the future for this person is the MRI-guided laser interstitial thermal therapy. This treatment modality has been supported by both the individual's consultant and a professor at one of the UK's leading Neurological Hospitals. However, the persons health trust has rejected funding this treatment as it is expensive and have used the current NICE guidelines as a justification with this rare form of epilepsy not listed. The individuals cost of medication is £4047.93 a year. This medication is not effective, the person still experiences debilitating seizures 8-10 times a day. This cost does not include admissions to psychiatric hospitals or community mental health services for treatment for his situational depression. In adding these costs together, it may be argued that the MRgLITT would not only be more cost effective across the person life span but would also provide the individual a chance to experience a better quality of life. Please can NICE revise the guidance to stipulate that this form of treatment should be considered for other types of epilepsy where drug therapies are not effective in controlling daily seizures. As a result, these seizures severely impede on an individual's abilities to perform daily living activities safely, engage in sustainable employment and detrimentally effect mental wellbeing.	
6	Consultee 5 NHS England Specialised Commissioning		NHS England Specialised Services' Paediatric Neuroscience Clinical Reference Group has reviewed the MRI-guided Laser interstitial therapy consultation document. It is recognises that the therapy is experimental and there is uncertainty around long term outcomes due to the relatively recent introduction of this technology. Some members had concerns regarding the evidence relating to risks from thermal injury. It was felt that more robust specialist arrangements needed to be stipulated perhaps recommending an Random Control Trial or National	Thank you for your comments. Our draft recommendation in 1.1 and 1.2 states that clinicians should use the procedure with special arrangements which includes informing clinical governance lead, informing patients clearly, taking consent and auditing outcomes. Section 1.5 of the draft guidance also recommends further research in the form of

			Registry. NHS England Specialised Services would recommend consulting more widely across both the private and public sector.'	randomized controlled trial, large case series or collaborative registries. IPAC noted your comments in relation to the risks from thermal injury. This adverse event has been reported in the studies added to table 2.
7	Consultee 6 Association of British Neurologists	**1**	We acknowledge that there is still limited published evidence of efficacy and risks of using LITT in epilepsy surgery but would like to add that the therapy is currently in fairly widespread use in other parts of the world, particularly the United States. In light of the fairly limited published data as well as the safety concerns raised, it seems reasonable that the intervention is initially offered by special arrangement, to allow collection of further data regarding safety and efficacy. For patients undergoing epilepsy surgery, the decision should already be taken by MDTs and these MDTs can also provide recommendations on either open surgery or LITT to patients as well. In the future, this may be an alternative to open surgery and an RCT would be useful. However, in view of difficulties recruiting patients to a previous RCT on stereotactic radiosurgery vs open temporal lobe resection, it may be difficult to recruit for an RCT on LITT vs open surgery as well. A National audit, collecting data from several centres will allow collection of larger cohorts to provide further data on safety and efficacy and should be encouraged. We consider that the provisional recommendations are a sound and suitable basis for guidance to the NHS.	Thank you for your comments. Consultee agrees with the draft recommendations in section 1. The consultee is supportive of a national audit approach. Section 1.3 recommends that ***'****Patient selection should be done by a multidisciplinary team experienced in managing drug-resistant epilepsy. This may include a neurologist, neurosurgeon, neurophysiologist, neuroradiologist and psychiatrist'.* Section 1.5 recommends *'further research could be in the form of randomised controlled trials, large case series or collaborative registries'.*

8	Consultee 7 Monteris Medical		1.1 The draft guidance states "Evidence on the safety of MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy shows there are serious but well recognised safety concerns". It is worth noting that when a patient is drug refractory and it has been determined that a surgical intervention is appropriate, (laser or open resection) there are safety concerns related to an open surgical resection (craniotomy) that are well documented in the literature. 1.4 Additional reference: Wu et al 2019 describes patient selection and appropriate targeting to achieve better seizure freedom outcomes. Wu, C. et al. The Effects of Anatomic Variations on Stereotactic Laser Amygdalohippocampectomy and a Proposed Protocol for Trajectory Planning: Neurosurgery 11, 345–357 (2015). Bermudez et al was recently published and describes the neuropsychological outcomes relevant to laser ablation : Bermudez, C. I. et al. Cognitive outcomes following laser interstitial therapy for mesiotemporal epilepsies. Neurology: Clinical Practice 10.1212/CPJ.0000000000000728 (2019) doi:10.1212/CPJ.0000000000000728. Regarding safety data of the procedure, an added reference for consideration comes from a multi-center prospective registry with some subjects included in the registry study diagnosed with medically refractory epilepsy. LAANTERN : Rennert, R. C. et al. Laser Ablation of Abnormal Neurological Tissue Using Robotic Neuroblate System (LAANTERN): Procedural Safety and Hospitalization. Neurosurgery (2019) doi:10.1093/neuros/nyz141. <u>Existing Assessments of the Procedure/Issues for Consideration by IPAC:</u> Regarding the letter to healthcare providers from FDA, to	Thank you for your comments. The safety statement in 1.1 makes the point that serious adverse events have been reported but they are well recognised within the context of this indication. It is not intended to infer that the procedure has more or fewer adverse events than other treatments for the condition. Thank you for your comments and bringing to our notice additional publications related to this topic. WU 2019 picked up in our update search has been added to table 2 in the overview. Bermudez 2019 (a small retrospective case series on cognitive outcomes) has been added to the appendix in the overview. Rennert 2019 reported the safety profile of stereotactic laser ablation mainly for primary intracranial neoplastic lesions (mainly high-grade gliomas and metastases) and included very few epilepsy patients. Therefore, this study has been added to the appendix in the overview. IPAC noted that since the implementation of the updated system/product, Monteris Medical has not received any complaints related to either topic. Page 20 in the overview, state that '*The two manufacturers that market MRgLITT devices, including Medtronic, and Monteris*

			clarify, a new Monteris Medical NeuroBlate design to eliminate any risk of unintended probe heating was cleared by FDA (510k reference K182036) in October 2018 with updated labeling enhancements to address MRI thermometry variability. Since the implementation of the updated system/product, Monteris Medical has not received any complaints related to either topic. <u>Ongoing Studies Registered on ClinicalTrial.gov:</u> Suggest adding this Prospective Multi-Center Real World Evidence Registry to the list of references as subjects with Epileptic/Seizure Foci are part of this study: Laser Ablation of Abnormal Neurological Tissue Using Robotic NeuroBlate System (LAANTERN) NCT02392078 https://clinicaltrials.gov/ct2/show/NCT02392078	*Medical, have also provided updated information with suggested procedural techniques for MRgLITT devices to reduce unintended thermal damage'.* The ongoing study termed Laser Ablation of Abnormal Neurological Tissue using Robotic NeuroBlate System (LAANTERN; Monteris Medical) has been added to the overview on page 22. It is collecting data on safety, efficacy, and quality of life data on a target population of 1000 patients with metastatic brain tumor, primary brain tumor or epileptic seizure foci.
9	Consultee 8 Medtronic	**3**	Thank you for assessing Laser Interstitial Thermal Therapy (LITT) for drug-resistant epilepsy . In addition to the published evidence reviewed as part of the primary IPAC meeting, please see below two new publications related to LITT recently published . References: Wu, Chengyuan; Sharan, Ashwini D.; Matias, Caio M. et al. Effects of surgical targeting in laser interstitial thermal therapy for mesial temporal lobe epilepsy: A multicenter study of 234 patients. Epilepsia (Series 4). Jun2019, Vol. 60 Issue 6, p1171-1183. 13p. DOI: 10.1111/epi.15565. Iahn Cajigas, Andres M. Kanner, Ramses Ribot et al. Magnetic Resonance–Guided Laser Interstitial Thermal Therapy for Mesial Temporal Epilepsy: A Case Series Analysis of Outcomes and Complications at 2-Year Follow-Up.World Neurosurgery. Jun2019, Vol. 126, pe1121-e1129. 9p. DOI: 10.1016	Thank you for your comments and bringing to our notice new publications related to this topic. WU 2019 picked up in our update search has been added to table 2 in the overview. Cajigas I et al (2019) picked up in our update search has been added to the appendix in the overview.
10	Consultee 9 Epilepsy Action	**3**	Epilepsy Action supports MRI-guided laser interstitial thermal therapy (MRgLITT) as a treatment option for	Thank you for your comments. IPAC noted that Epilepsy Action supports this treatment

			epilepsy. We have spoken to consultant neurologists at Greater Ormond Street Hospital. This is the only hospital in the UK where this treatment is currently available. Neurologists at GOSH have been carrying out the procedure since acquiring the equipment last year, and have successfully treated 5 patients. As the procedure is not currently NHS tariffed, they have so far relied on charitable funding. **Safety** The treatment has been available in the US for 10 years and data exists on its effectiveness and efficacy. The procedure has been found to have led to reduced mortality, reduced hospital stays post-surgery and reduced scarring (https://www.sciencedirect.com/science/article/pii/S1525505012003629). Studies have shown that MRgLITT has significant advantages over open surgery in that it produces less immediate discomfort and disability, while allowing for greater preservation of functional tissue (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5233636/). As the procedure is much more focused and less invasive than open surgery, the potential for damage to the surrounding areas of the brain are minimised. MRgLITT provides an extremely well-demarcated region of ablation and is not associated with long-term radiation risks (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5627747/). Laser ablation allows minimal corridor-related morbidity and provides better visualisation of the border between the hypothalamic hamartoma and the surrounding hypothalamus. Additionally, the focused nature of the MRgLITT procedure means that it can be used on patients who would not have	option. It is not within the remit of the programme to evaluate the cost effectiveness of interventional procedures, or to advise the NHS on whether interventional procedures should be funded. IPAC considered the points about the safety of the procedure, including the points about mortality and surgical morbidity, hospital stays, reduced scarring, less disability and discomfort and reduced neurocognitive effects. IPAC also considered the comments related to patient selection. Studies referenced by the consultee are added to the overview. Curry DJ 2012 has been included in systematic review added to table 2. Kang 2017, Shukla 2017 and North 2017 are reviews and have been added to appendix in the overview.

			been considered for other forms of brain surgery, due to concerns about the potential risk of further damage. This would provide a valuable treatment option for patients with drug-resistant epilepsy and could minimise morbidity and mortality in these patients. High-risk surgical patients may also benefit from this minimally invasive procedure if surgical resection is not a viable option. The MRgLITT also reduces the need for pain medication post-surgery (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5627747/). Analgesic requirements are lower compared to open surgical resections which may reflect faster recovery times. The procedure requires a much smaller burr hole than other surgeries, and therefore patients experience less scarring than with other procedures. MRgLITT also represents a lack of adverse neurocognitive effects compared to temporal resection. Laser ablation offers comparable outcomes with a reduction in surgical morbidity ranging from profound (hypothalamic hamartoma) to moderate (mesial temporal lobe epilepsy) (https://www.sciencedirect.com/science/article/pii/S1042368017300839).	There are no prospective randomised comparative studies between MRI-guided LITT and other surgical techniques, minimally invasive techniques (such as radio-surgical techniques,) or non-invasive techniques (such as MRI-guided focused ultrasound surgery) for both adults and children. Only matched historical controls have been used to make comparisons. Most of the studies were small cohort studies. 2 meta-analyses mainly focused on drug-resistant or medically intractable mesial temporal lobe epilepsy with curative intent mainly in adult patients. Studies included in these analyses were mainly retrospective studies with small sample size and short-term follow-up. Section 3.7 of the draft guideline states that *'the committee was advised that, in the future, this procedure may be offered as an alternative to drug treatment for epilepsy'.*
11	Consultee 9 Epilepsy Action		**Cost** The procedure has the potential to lead to significant cost savings, despite having a relatively high up-front cost of around £10k per patient. The decreased length of hospitalisations for patients who have undergone MRgLITT is well documented, providing hospitals with cost savings here to help balance against the costs of this new technology. Compared to a 2-3 week stay in hospital for patients who have undergone more conventional surgery, the recovery	Thank you for your comments. It is not within the remit of the programme to evaluate the cost effectiveness of interventional procedures, or to advise the NHS on whether interventional procedures should be funded.

			period for MRgLITT is 2-3 days. This not only provides significant cost savings through reduced hospital stays for these patients, but also means that the wider availability of hospital beds could be improved. Furthermore, we understand that in many cases in the US, patients are able to return home the same day as undergoing the procedure. It is hoped that through developing further expertise in this treatment, such results could be replicated in the UK, further reducing the use of hospital beds. The benefits to patients of shorter, even same day treatment, and reduced recovery times would be invaluable, and MRgLITT would provide patients with more choice of treatment. In addition, expense can be expected to decrease over time as more centres develop expertise in the procedure and the technology becomes more readily available. **Outcomes** Studies have concluded that MRgLITT appears to be a safe, effective initial treatment option in the treatment of medication-refractory mesial temporal epilepsy MTE, achieving seizure freedom rates of 61.5% at 2 years (https://www.sciencedirect.com/science/article/pii/S1878875019306941). The current data suggests that seizure-free outcomes can be achieved with MRgLITT similar to open surgery (albeit at slightly lower rates) while reducing procedure time, hospital stay, and pain control. The minimally invasive nature of the procedure does not preclude a repeat intervention if necessary (MRgLITT or open surgery) (https://www.sciencedirect.com/science/article/pii/S0967586	4 studies listed (Cajigas I 2019, Waseem 2017, Shimamoto S 2019, Le S 2018) are added to the appendix in the overview.

			816308360). There is data to suggest that MRgLITT has the potential to offer benefits when treating drug-resistant epilepsy because of mesial temporal sclerosis, hypothalamic hamartoma, cavernous hemangioma and small cortical dysplasias and malformations (https://www.ncbi.nlm.nih.gov/pubmed/30694919). One study tracking mesial temporal lobe epilepsy (mTLE) cases treated with MRgLITT found that 97% of patients had more than a 50% reduction in their baseline seizure frequency, with 76% having more than a 90% reduction in baseline seizure frequency. There were no patients with worsening seizures following the treatment (https://www.sciencedirect.com/science/article/pii/S1525505018306097). **Conclusion** Given the experience of MRgLITT in the US and Great Ormond Street Hospital, Epilepsy Action believes that this procedure should be made available on an NHS tariff given the potential for improved safety, reduced recovery times, the treatment of people with intractable epilepsy and the potential for long term cost savings.	Committee noted your views in their deliberations. As there is uncertainty about the efficacy of this procedure, recommendations in 1.1 and 1.2 suggest that clinicians should use the procedure with special arrangements which includes informing clinical governance lead, informing patients clearly, taking consent and auditing outcomes. These recommendations allow patents to access a procedure with appropriate safeguards and caution. The committee does not have a remit to determine the availability of a procedure on an NHS tariff.
12	Consultee 10 Public	**General**	This therapy will help those, where conventional surgery would mean their peripheral vision would be lost. Epilepsy surgery has significant risks itself however to lose your sight is a step to far. Plus why should those with epilepsy not be	Thank you for your comments. Committee noted your views in their deliberations. A committee comment was added to section 3.8 as follows: '*The committee was pleased*

			given a chance to live their life without the burden of seizures having to be factored into everything they do.	*to receive consultation comments from patients and their advocates'.*
13	Consultee 11 Family member	**General**	I am making this comment as a close relative of someone who has a harmatoma. I am acutely aware that he struggles to control his epilepsy through medication and that this impacts hugely on his day to day living. He has difficulty functioning in any work environment and his position is hugely prejudiced as a result of being unable to control his condition using standard medication. I see the opportunities afforded by this proposed treatment as being thoroughly worthy of consideration, not just to him but to others in similar circumstances.	Thank you for your comments. Committee noted your views in their deliberation and considered the comment about the use of this treatment in relation to hamartomas. A committee comment was added to section 3.8 as follows: '*The committee was pleased to receive consultation comments from patients and their advocates'.*
14	Consultee 12 Public	**General**	Drug-resistant epilepsy is a seriously debilitating condition impacting on an individual's sleep, ability to work (due to possible seizures) and all-round general quality of life. Patients may be given in excess of 3,500 tablets per year on top of additional minerals. Over the lifetime of a patient this is around 280000 tablets which must cost in excess of the treatment ascribed here and therefore be preferential in terms of QALYs. If this treatment is non-invasive and has a good chance of success then in terms of quality of life and in terms of patient well-being and productivity over their lifespan this must surely be preferential.	Thank you for your comments. Committee noted your views about the benefits to quality of life and patient well-being and productivity over their lifespan. A committee comment was added to section 3.8 as follows: '*The committee was pleased to receive consultation comments from patients and their advocates'.* It is not within the remit of the programme to evaluate the cost effectiveness of interventional procedures, or to advise the NHS on whether interventional procedures should be funded.
15	Consultee 13 Carer (parent of consultee 20)	**General**	As the parents of someone suffering with epilepsy who struggles daily, he has always needed monitoring and helping because of his seizures. The impact on his life has been huge and has limited his job and life opportunities. We are very concerned about his future or where he will get this much needed support. My son struggles in all areas with every day physical, mental and financial tasks, as he strives for future independence.	Thank you for your comments. Committee noted your personal experiences, and those of your son's, in their deliberations. The committee noted the debilitating nature of daily seizures and the wider impact on job and life opportunities, and the ability to live an independent life, and also the impact on mental health. The committee also noted

			He has been on assortment of over 13 different medication at a high dosage combinations. He has never been seizure free and medication has ceased to be effective over time. He has been on medication for over thirty years. The side effects of medication have debilitating effects on him and the finical costs of medication must be considered as an issue for the NHS. We are also concerned about his mental health due to high stress and anxiety if his epilepsy conditions does not improve. MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy offers a safer and more effective way of dealing with his mental health and epilepsy and potentially allows him to lead a safer, fuller and better life.	comments regarding the side effects of medication. A committee comment was added to section 3.8 as follows: '*The committee was pleased to receive consultation comments from patients and their advocates'.*
16	Consultee 14 Public	**General**	I believe that this will be a great opportunity to allow people with epilepsy to have a new view on life and allow them to be able to accede with there ambitions, this is if the risk taking for this treatment are understood and that risk don't out-way the positives. As at the end of the day it's a life threatening operation. But with success this operation can change many people's life's forever.	Thank you for your comments. Committee noted your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
17	Consultee 15 Public	**General**	I think this procedure would be of great benefit to many people. Especially considering the quality of life they could live after having this procedure rather than in comparison to the risks and further damage that's could be caused by other potential operations. I think this is financially a better solution as from what I understand it could help many brain issues and complications. Also with the reduced side affects this would mean less future treatment for patients.	Thank you for your comments. Committee noted your views on the potential quality of life benefits, and the risks of side effects in their deliberations. A committee comment was added to section 3.8 as follows: '*The committee was pleased to receive consultation comments from patients and their advocates'.*
18	Consultee 16 Public	**General**	I believe that this procedure should be available on the NHS. I have read the project information which I fully support.	Thank you for your comments. A committee comment was added to section 3.8 as follows: '*The committee was pleased to receive consultation comments from patients and their advocates'.*

19	Consultee 17 Public	**General**	I would like to lend my support to this procedure being offered to patients whose epilepsy has been unable to be controlled by medication. The document appears to balance the information regarding the benefits to patients, with the possible risks and post operative complications.	Thank you for your comments that guidance appears to balance the information regarding the benefits to patients, with the possible risks and postoperative complications. auditing outcomes. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
20	Consultee 18 Public	**General**	As a long-time family friends, we have seen the negative effects of this condition and the lessening effectiveness of the accompanying medication, to the extent that he is now fitting more often , sometimes several times a night, and of course during the day. This is naturally leading to sleep deprivation and an increasing inability to concentrate, impacting on both his general and mental health. As such, this also prevents him from gaining long-term employment. He is, of course, unable to drive, which further limits his employment prospects. He is living with his parents and reliant on them in the most part for transport and day to day support. As they are now elderly and not in good health, this is proving increasingly problematical. It is extremely unlikely that he will be able to support himself in the future both in terms of housing and day to day living if his condition is not improved. The MRI laser guided thermal therapy would provide massive improvement without the severe side effects of neurosurgery. Currently his combined medication costs over £4000 per annum and as it is unlikely that he will ever be able to support himself independently in the current circumstances, a further and long-term drain on social services in the	Thank you for your comments. Committee noted your views on the social and psychological impact of epilepsy, as well as the long-term outcomes. Committee also noted the comments about side effects of the procedure. A committee comment was added to section 3.8 as follows: '*The committee was pleased to receive consultation comments from patients and their advocates'.*

			shape of benefits, living assistance and inevitably carers, is practically certain.	
21	Consultee 19 Public	**General**	I am married to a person who suffers epilepsy, his condition and current medication causes him many different side effects. The hardest to deal with being his mental health as he deals with depression and anxiety. He also struggles in his every day life, as he is constantly tired, he has never been seizure free and his prescription has been changed many times, this is because his medication stops working for him over time. This condition also denies him the opportunity to achieve professionally as he struggles with high stress levels which means he's jobs prospects are limited by both the epilepsy and the side effects of his medication. This brings uncertainty over our future as we are trying to build a family and a life together. MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy would be a more effective way for him to recover control over his life. It would represent the opportunity to live his life to the fullest and be able to gain the independence he so strongly looks.	Thank you for your comments. Committee noted the comments about the effects of epilepsy on mental health and on quality of life, employment and independence. A committee comment was added to section 3.8 as follows: '*The committee was pleased to receive consultation comments from patients and their advocates'.*
22	Consultee 20 Patient	**General**	I have been suffering from Gelastic Epilepsy every day of my entire life and now I'm approaching 40 years of age and desperately need to find drastic improvements. I have multiple seizures during the day and night whilst trying to sleep, which disrupts all aspects of my life and leaves me struggling to function from day to day. My epilepsy is caused by a Hypothalamic Hamartoma, benign Brain Tumour and has never been under control, even with the wide variety and combination of drugs at high dosages. I have also suffered from mental health and wellbeing problems for many years and this is recorded as a side effect of my form of epilepsy. I am also taking medication for my stress and anxiety and hopeful that this might help. I do not remember the last time I had a proper night's sleep as my seizures wake me up every couple of hours or even	Thank you for your comments. Committee noted and discussed your diagnosis, symptoms and views in their deliberations. The committee also noted the impact of epilepsy on quality of life, relationships and employment, as well as the impact of the side effects of medication. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*

			more frequently and my mental health causes me problems with getting to sleep and effectively resting. My parents are very concerned about my future or where I will get the support I strongly need and this causes increased stress and much anxiety to my family as well as myself. I have always needed close monitoring, support and help. Safety is always an issue for me when socialising, working and even simple daily living tasks, like eating, drinking, cooking and getting out and about. I receive support from my parents and my wife who is currently training and earning a wage for the both of us. I also get regular help from professionals such as my GP Doctors surgery, a talk plus mental health counsellor, radiologist, neurologist specialist nurse and my neurologist consultant, as well as the financial NHS support for medication which would otherwise for me be substantial each year. I also receive help from Citizens Advice Bureau, Richmond Fellowship, government careers support, governmental financial benefits. I worry how I will cope in the future, especially as my parents get more frail with age and illness and I am trying to build my independent life. I hope to have a family of my own one day but currently am unable to support my wife on my own and she often has the additional burden of taking care of me whilst trying to work and study. My condition has prevented me from gainful long term employment and I have never been employed for more than two years. I have also made very few friends since leaving university and have struggled to socialise and maintain existing friends and relationships. During seizures I can become completely absent or/hypoactive but either way may still not be aware of what I'm doing or what is happening. There is odd laughter, giggling and manic breathing that sound unpleasant rather than joyful. The outburst can lasts up to 5mins. I can display	

			some twitching, strange eye movements and struggle to focus visually. There can be lip smacking, fidgeting or mumbling, as well as facial colouration changes (pale or red). My epilepsy results in disorientation, unable to respond, tiredness and disrupted sleep resulting in more seizures throughout the day, concentration impairment, further anxiety and stress, depression, memory impairment, hygiene and anxiety issues, communication and socialisation issues. Recovery can take up and sometimes beyond 30 minutes. This all clearly creates safety issues. My medication has a range of side effects including, drowsiness, speed impairment (physically and mentally), clumsiness, mood swings, anxiety and depression, headaches and weight fluctuations. MRI-guided laser interstitial thermal therapy is exactly what is needed as my epilepsy is drug resistant and even medication that has worked for me in the past seems to have a short effectiveness. I have previously lost complete seizure control and my family stopped counting my seizures once I reached over 50 seizures whilst awake. Conventional brain surgery has been discussed with me but the neurosurgeon and neurologist consultant both agreed this held a high risk potential of lasting brain damage, especially due to the position of my brain tumour and the nature of the surgery. My medical conditions and related medication has caused me to struggled to create my own more independent life and have a fairer safer standard of living. This surgery seems currently the only way for me to achieve a more safe and fulfilling, dignified quality of life. I wish to have the chance to reduce the problems I suffer with every day physical, mental and financial tasks. The epilepsy impact on my life has been huge and has limited job and life opportunities and future independence. Other obvious drawbacks of my condition include being unable to drive	

			which is important for many jobs. Please help me by getting this surgery!	
23	Consultee 21 Public (sister of consultee 20)	**General**	My brother has suffered with epilepsy for all of his life. He has never been seizure free and as such, has impacted his day to day life in a negative way. His seizures affect him in all aspects of his life including employment, potential career development, financial freedom, long term future plans, relationships and being dependent on others. His epilepsy is drug-resistant and costing the NHS thousands over the years. The day to day prescription that he takes is debilitating on his mental health and day to day brain function for normal daily activities. This will not change. Unless he is given access to the MRI-guided laser interstitial thermal therapy which potentially allows him to lead a normal life.	Thank you for your comments. Committee noted your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
24	Consultee 22 Public	**General**	I strongly support the use of this procedure as long as it has patients consent. It will be a positive move for this to be provided by the NHS.	Thank you for your comments. Committee noted your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.* Our draft recommendation in 1.1 and 1.2 suggests that clinicians should use the procedure with special arrangements which includes informing clinical governance lead, informing patients clearly, taking consent and auditing outcomes.
25	Consultee 23 Public	**General**	My best friend of 20 years has suffered from epilepsy since I've known him. I've observed his struggles at every stage of progression from childhood to adulthood, as a result of the debilitating mental side effects of the many drugs he's been prescribed. He has struggled with the demands of education, with finding a job and with gaining independence. He often needs help with simple tasks. His mental health is deteriorating and he is losing hope. This	Thank you for your comments. Committee noted your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*

			therapy could be absolutely life changing for him, and potentially allow him to start living a normal life.	
26	Consultee 24 Public	**1 and General**	The use of Modality MRI Guieded Laser Intestitial Thermal Therapy (MRgLITT) has been identified as minimally invasive, effective and increasingly safe treatment for patients with medically intractable epilepsy. Patients given MRgLITT are provided the potential to experience seizure freedom. Currently under NICE guidelines, MRgLITT is not recommended to patients such as those with Hypothalamic Hamartomas (HH) despite the medical research that shows gelastic seizuers very respond to anti epilepsy drugs. The use of MRgLITT in countries such as the USA and Canada provides research data that demonstrates the high effectiveness of treatment in not only pediatric but also adult patients with significant levels of seizure free patients post operative. The results suggest that these patients are remaining seizure for a number of years, possibly longer or even permanently. Patients with this epilepsy deserve the opportunity to have access to treatment that will allow them to experience a reduced seizure or seizure free life. Complications of HH mean individuals can experience cognitive delays and miss important milestones such as crawling, walking and talking. They also have a prognosis of deteriorating cognitive function and behavioural symptoms. The financial impact means that the NHS is currently paying for drugs that have been identified as ineffectual. With increasing interventions required to support individuals including further medical support from psychiatrists, psychologists and other community based medical professionals. On top of this the government is also likely to be paying out for lifelong disability benefits. The comorbidity of the epilepsy alongside behavioural and cognitive dysfunctions makes living with HH very	Thank you for your comments. IPAC considered your comments about the use of this procedure for hypothalamic hamartomas and gelastic seizures and amended Section 3.5 as follows: *'The committee noted that, in adults, the procedure has primarily been used to treat temporal lobe epilepsy and in children for hypothalamic hamartomas'*.Committee also noted comment that this procedure is in use in countries such as USA and Canada. Section 3.6 of the draft guidance states that 'the committee was informed that the procedure is much less invasive than open surgery'. Section 3.7 in the draft guidance states that 'the committee was advised that, in the future, this procedure may be offered as an alternative to drug treatment for epilepsy'. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.* IPAC does not consider the cost of the procedure. It is not within the remit of the programme to evaluate the cost effectiveness of interventional procedures, or to advise the NHS on whether interventional procedures should be funded.

			challenging not only for the individual but their family. Further complications for Patients are include depression and anxiety. This can result in patients requiring considerable support to function on a daily basis. These individuals may find it challenging to maintain employment and, in some instances, due to the symptom of rage, struggle to maintain social relationships. It is my request that NIICE consider recommending MRgLITT to a wider population of patients. This would allow for the provision of effectual treatment to patients with epilepsy where medication is not controlling seizures. By doing so, this will provide health authorities clear guidelines on offering this treatment for these patients and a positive outcome for what is a very debilitating medical condition.	
27	Consultee 25 Carer	**General**	The effects of regular seizures on a patient are both physical and mental. Where these seizures have proved to be drug resistant surgery remains a last resort. However in some cases using regular surgical procedures the only way to access the site of the epilepsy is to cut through good brain matter to access the area. A procedure that offers surgery where the alternatives are debilitating is an opportunity not to be missed and from the patients viewpoint priceless. However the economic argument, even where only a mild improvement is achieved is strong as each seizure carries risks and each patient requires medication. Where these seizures and medication are reduced the financial benefits to the NHS as well as to the economy as a whole are clearly positive. The implications of the larger seizures are even more dramatic in terms of economics as the potential costs to the NHS and again the wider economy are significant. Epileptics unable to travel and or work due to seizures may be able to do both and therefore contribute more to the public finances.	Thank you for your comments. Committee to considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.* It is not within the remit of IPAC programme to evaluate the cost effectiveness of interventional procedures, or to advise the NHS on whether interventional procedures should be funded.

			Whilst initially it is accepted the costs may be high, with wider usage and acceptance surely these costs would reduce. This may get to the point where there are other benefits that would reduce recovery times and therefore reduce NHS costs further.	
28	Consulte 26 Patient		As a potential candidate for this surgery I believe that it would be revolutionary and life changing, not to mention the long term cost saving on AED's should potential candidates be cured of their epilepsy. This surgery would also prevent the loss of peripheral vision that would happen should candidates have the conventional surgery required deep within the occipital lobe (such as the surgery I would need). This could provide independence to people whose epilepsy cannot be controlled by typical medication.	Thank you for your comments. Committee considered your views that the treatment could be potentially life changing and also the potential risk of loss of peripheral vision in other surgical approaches. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
29	Consultee 27 Carer	**General**	This procedure would transform the quality of life for [redacted] who is very restricted in what she can do at the moment.. it would benefit many individuals for who medication is not effective	Thank you for your comments. Committee considered your views in their deliberations and note the potential benefit on quality of life. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
30	Consultee 28 Public	**General**	Vital this is made available to enable this life changing procedure to be carried out without the risks to patients of the current procedures	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
31	Consultee 29 Public	**General**	This treatment would transform a person's living quality without being too invasive... more economical than years of further tests and drugs	Thank you for your comments. Committee considered your views in their deliberations. IPAC does not consider cost. A committee comment was added to section 3.8 as follows: *The committee was pleased*

				to receive consultation comments from patients and their advocates.
32	Consultee 30 Public	**General**	I fully and wholeheartedly endorse and support this new surgery for epilepsy. It gives those who have exhausted all other possible options and have despaired at the lack of effectiveness of drugs the possibility to have their epilepsy cured by a less barbaric and invasive surgery which would leave those who have normal surgery with less eyesight and a poorer quality of life. This also means that this surgery will also have long term effective benefits, as those who have the luxury of this new surgery won't need the post operative care and future treatments that those who have the current surgical procedures would need, therefore proving much more cost effective and kinder on the individuals themselves who have already suffered more than the majority of people ever will in their lives. It is a basic human right to be entitled to the best possible medical treatments out there, so it is vital that this is granted funding so that not everyone at least has the option of considering this epilepsy surgery.	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.* It is not within the remit of the programme to evaluate the cost effectiveness of interventional procedures, or to advise the NHS on whether interventional procedures should be funded.
33	Consultee 31 Public	**General**	I've lost young friends who has suffered with this condition all there lives with ineffective medication and now this surgery is available that, not only can save lives, but can give quality to lives is incredible and no-one should be denied the rights to choose this option of surgery if it's available. We are advancing in medical and these breakthroughs are not just incredible but can give back hope to so many people out there who are living in fear for their lives...each epelisy episode not knowing if it's their last. We should not be selecting who is entitled but should be free for anyone who can have their lives back. Thus should be free on NHS.	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.* It is not within the remit of the programme to advise the NHS on whether interventional procedures should be funded.
34	Consultee 3 Public	**General**	This is very important and must be implemented! Will help a lot	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased*

				to receive consultation comments from patients and their advocates.
35	Consultee 33 Public	**General**	This treatment from the evidence shown, demonstrates this can be life changing for people who have epilepsy where other treatments are not effective in controlling the condition. I would be delighted if this could be available.	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
36	Consultee 34 Public	**General**	Looks excellent	Thank you for your comments. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
37	Consultee 35 Public	**General**	I am aware of a young person for whom there is no other hope of treatment and this could transform her life and others like her	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
38	Consultee 36 Public	**General**	If this treatment gets approved, the difference it would make to the people affected would be indescribable. It would allow epileptics to have a chance at living a normal life undisturbed by seizures, side effects and constant medications. It would also save the NHS money long term as the reduction and hopefully removal of drugs would mean fewer drugs would have to be dispensed, this would also mean less time in hospitals for consultant visits and scans which would reduce hospital waiting times in the relevant departments.	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
39	Consultee 37 Public	**General**	I believe that this procedure should be adopted by the National health for lots of reasons predominantly for quality of life without the use of evasive drugs.	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*

40	Consultee 38 Public	**General**	For people living with drug resistant epilepsy experiencing uncontrolled seizures which risk their life and severely effect the quality of their life, MRI-guided laser interstitial thermal therapy should be available. The alternative treatment of open surgery has a lower success rate of freedom from seizures together with higher rate of further damage to the brain during the procedure, if in fact an option at all to a particular individual. The procedure overall would hopefully alleviate the need for ongoing medication and further treatments in the future	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
41	Consultee 39 Public	**General**	the following operation will hopefully eradicate the epilepsy so my friend can begin to live a normal everyday life.	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*
42	Consultee 40 Public	**General**	This intervention if approved and accepted by the NHS could substantially improve the lives of patients with this type of epilepsy.	Thank you for your comments. Committee considered your views in their deliberations. A committee comment was added to section 3.8 as follows: *The committee was pleased to receive consultation comments from patients and their advocates.*

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