

NHS ENGLAND SPECIALISED SERVICES CLINICAL PANEL REPORT

Date: 19th June 2024

Intervention: gamma knife stereotactic radiosurgery

Indication: essential tremor refractory to medication (adults)

URN: 2342

Gateway: 2, Round 1

Programme: Cancer

CRG: Radiotherapy & Neurosurgery

Information provided to the Panel

Policy Proposition

Evidence Review completed by Solutions for Public Health

Clinical Priorities Advisory Group (CPAG) Summary Report

Evidence to Decision (EtD) Summary

Equalities and Health Inequalities (EHIA) Assessment

Patient Impact Assessment

Blueteq® Form – adult initiation

Policy Working Group (PWG) Appendix

This Policy Proposition recommends the use of gamma knife stereotactic radiosurgery (SRS) for patients with essential tremor (ET) refractory to medication (adults). Essential tremor is the most common movement disorder, causing parts of the body to move in an uncontrolled and repetitive manner. Medication is the first line of treatment option for patients with essential tremor. However, drug treatments stop working for between a quarter and a half of patients. Surgical intervention in ET can then be considered if symptoms are severe. The commissioned current first line surgical treatment is deep brain stimulation (DBS). This intervention is not suitable for some patients, at which point a routinely commissioned option that may be considered is MR guided focussed ultrasound thalamotomy. This policy proposition suggests stereotactic radiosurgery as an alternative second line treatment option. There are an estimated 100-150 patients in England per year who would be eligible for this treatment.

An evidence review was completed which included eight papers: one systematic review with network meta-analysis (NMA), five case series (four with pre- and post-treatment data, one with change from baseline only), and two cost analyses.

Outcomes that were considered critical and important to decision making were presented to Panel members. The evidence was of very low certainty for all reported outcomes, mainly due to the lack of comparative data. One study provided very low certainty non-comparative evidence that there is a statistically significant improvement from baseline in quality of life for people with medication-refractory ET at 12 months following unilateral GK SRS. The studies

reported non-comparative statistically significant improvement in tremor severity from baseline measurement, reporting improvement in activities of daily living. Adverse events (AEs) were mainly reported as motor weakness and dysarthria.

The proposition and the supporting documentation were presented to Clinical Panel members. Panel members debated at length that the decision point for the use of gamma knife SRS or other existing treatments, such as Transcranial MRI guided ultrasound thalamotomy (TcMRgFUS), is not clear. There are no criteria currently written in the policy regarding this. It appears this is a clinical decision but not defined how/why this is arrived at. The multidisciplinary team (MDT) decision needs to be joint across the treatment centres so the best treatment pathway for the patient is chosen, rather than the facilities available within a given centre driving the decision.

Concern was expressed regarding the potential expansion of services given this is a highly specialised service delivery and the eligible patient numbers very low. These centres would need to be designated Tier 4 and specialist movement disorder centres.

EHIA – no amendments requested. It was noted that this condition is more common in the older population.

PIA – no amendments requested.

Recommendation

Clinical Panel recommends that this proposition returns to a future panel meeting for further consideration.

Why the panel made these recommendations

Panel members agreed that the evidence base, although non-comparative, demonstrates clinical benefit however, the proposition as currently written does not define how a decision is made regarding which treatment is most appropriate for the patient.

Documentation amendments required

General:

- Expand the Policy Working Group to ensure it includes membership of clinical leads from the current focused ultrasound services.
- Programme of Care leads should work together to define T4 centres and service delivery.

Policy Proposition:

- The proposition needs to clearly define the position of this treatment in the clinical pathway compared to other treatments available, and the criteria for determining this.
- The number of eligible patients for this specific treatment needs defining.

Blueteq™ Form:

- A standard criterion needs to be added within the stopping criteria of the Blueteq forms.

Declarations of Interest of Panel Members: One received

Post Panel Amendments

General		
Panel Comment	Amendment	Page number (if applicable)
Expand the Policy Working Group to ensure it includes membership of clinical leads from the current focused ultrasound services.	The clinical leads from both centres have been joined the PWG and contributed to the policy proposition.	n/a
Programme of Care leads should work together to define T4 centres and service delivery.	The implementation section of the policy proposition now states that all patients must be discussed at a joint TcMRgFUS and GK SRS MDT to determine suitability for GK SRS. This has been reflected in the updated patient pathway.	Policy proposition P4
Policy Proposition		
The proposition needs to clearly define the position of this treatment in the clinical pathway compared to other treatments available, and the criteria for determining this.	GK SRS is for patients who are not suitable for TcMRgFUS. The inclusion criteria now states: The patient is not suitable for TcMRgFUS e.g. Patient has a skull density ratio that is not compatible with TcMRgFUS on a pre-procedure CT head scan. Bluteq™, EtD document and patient pathway updated to reflect this change.	P4, P5
The number of eligible patients for this specific treatment needs defining.	The epidemiology and needs assessment now states: Approximately 50 patients per year are not eligible for TcMRgFUS and would be appropriate for consideration of gamma knife stereotactic radiosurgery.	P4
Bluteq™ Form:		

A standard criterion needs to be added within the stopping criteria of the Blueteq forms	This treatment is performed in a single session, therefore stopping criteria is not applicable.	n/a
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