

# Clinical Priorities Advisory Group Summary Report

|                          |                                                                                  |
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| Agenda item              | 3.3                                                                              |
| Date of Meeting          | 13/05/-15/05/2026                                                                |
| Title of the Proposition | Stereotactic radiosurgery for essential tremor refractory to medication (adults) |
| Unique Reference Number  | 2342                                                                             |
| Programme of Care        | Cancer                                                                           |
| Clinical Reference Group | Radiotherapy and Neurosurgery                                                    |
| Service/treatment status | delegated                                                                        |

## Action requested

Support the adoption of the policy proposition

Recommend its relative prioritisation.

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## Summary of the proposition:

Essential tremor is the most common movement disorder. It causes parts of the body to move in an uncontrolled and repetitive manner, most commonly affecting the arms and hands. Drug treatment is the first line therapy for essential tremor. However, drug treatment will stop working for between a quarter and half of patients. Surgical intervention such as deep brain stimulation (DBS) or transcranial magnetic resonance guided ultrasound

Unique reference number: 2342

thalamotomy (TcMRgFUS) is offered to patients whose symptoms are significant and severe and have not responded to medication. This policy proposition recommends that this new treatment is made available for patients with medication refractory essential tremor (ET) who are not suitable for TcMRgFUS.

Stereotactic radiosurgery (SRS) is an alternative method of producing a focal lesion in the brain by delivering very highly focussed radiation to the ventralis intermedius (VIM) nucleus of the thalamus, typically targeting one side to alleviate the tremor on the most severely affected side. The patient is awake during the procedure in which a stereotactic frame is first fixed to the patient's head and CT/MRI images acquired before treatment is delivered. It is usually done as a day case and the procedure takes approximately 1 – 1.5 hours. It is a minimally invasive neurosurgical procedure.

## Clinical Panel recommendation:

The Clinical Panel recommended that the policy proposition progress as a routine commissioning policy.

## Assurances

| The committee is asked to receive the following assurance: |                                                                                                                                                      |                                     |
|------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|
| 1.                                                         | The Deputy Director of Clinical Effectiveness confirms the proposition has completed the appropriate sequence of developmental and governance steps. |                                     |
| 2.                                                         | The Deputy Director of Cancer Programme confirms the proposition is supported by the following documentation (please tick the box where applicable)  |                                     |
|                                                            | Draft Clinical Commissioning policy proposition                                                                                                      | <input checked="" type="checkbox"/> |
|                                                            | Evidence Review                                                                                                                                      | <input checked="" type="checkbox"/> |
|                                                            | Public Health Evidence Report                                                                                                                        | <input type="checkbox"/>            |
|                                                            | Evidence to Decision Making (EtD) Summary                                                                                                            | <input checked="" type="checkbox"/> |
|                                                            | Equalities and Health Inequalities Assessment (EHIA)                                                                                                 | <input checked="" type="checkbox"/> |
|                                                            | Prior Approval Form                                                                                                                                  | <input checked="" type="checkbox"/> |
|                                                            | Engagement Report                                                                                                                                    | <input checked="" type="checkbox"/> |
|                                                            | 13Q Assessment and Patient & Public Voice Assurance                                                                                                  | <input checked="" type="checkbox"/> |
|                                                            | Clinical Panel Report                                                                                                                                | <input checked="" type="checkbox"/> |
|                                                            | Policy Working Group membership                                                                                                                      | <input checked="" type="checkbox"/> |
|                                                            | Other (please state if required)                                                                                                                     | <input type="checkbox"/>            |

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| 3. | The Deputy Director of Finance (Specialised Commissioning) confirms that the Impact Assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal. |
| 4. | The Director of Clinical Commissioning (Specialised Commissioning) confirms that the Service and Operational Impact Assessments have been completed.                                      |
| 5. | The Deputy Director of Quality and Nursing (Specialised Commissioning) confirms that the proposed quality indicators have been adequately defined (where applicable).                     |

## Evidence Review Summary

**In people with medication refractory essential tremor, what is the clinical effectiveness and safety of unilateral thalamic Gamma Knife Stereotactic Radiosurgery (SRS) compared with current standard care?**

| Outcome                                                                      | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Clinical Effectiveness</b>                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Critical outcomes</b>                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Quality of life</b><br><b>Certainty of evidence:</b><br>Very low          | <p>Quality of life is important to patients as it provides an indication of an individual's general health and their self-perceived well-being. Measurement of quality of life can help inform patient-centred decision making.</p> <p>In total, one case series presented non-comparative results for quality of life at 12 months after unilateral GK SRS for people with medication-refractory ET.</p> <p><b>At approximately 12 months follow-up</b></p> <ul style="list-style-type: none"> <li>One case series<sup>1</sup> (Bolton et al 2022) reported a <i>statistically significant</i> improvement from baseline in quality of life for 34 people with medication-refractory ET who underwent unilateral GK SRS. The mean±SD (range) QUEST score<sup>2</sup> improved from 45.46±16.4 (12 to 80) before radiosurgery to 23.16±16.57 (1 to 57) at 12 months after GK SRS; a change of -24.79±13.21 (-47 to -2); p&lt;0.0001 (<b>VERY LOW</b>)</li> </ul> <p><b>One study provided very low certainty non-comparative evidence that there is a <i>statistically significant</i> improvement from baseline in quality of life for people with medication-refractory ET at 12 months following unilateral GK SRS.</b></p> |
| <b>Improvement in tremor severity scale</b><br><b>Certainty of evidence:</b> | <p>This is important to patients because an improvement in their tremor suggests that treatment has been successful, and their symptoms will be improved.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

<sup>1</sup> It is not clear from the text whether this was a prospective or retrospective case series.

<sup>2</sup> QUEST scores range from 0 to 100, with benefit indicated by a lower score.

| Outcome  | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
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| Very low | <p>In total, one NMA reported a formal indirect comparison (and non-comparative data from a SR), and 5 case series<sup>3</sup> reported non-comparative results for improvements in tremor severity scale (using the FTM TRS<sup>4</sup>) for people with medication-refractory ET who underwent unilateral GK SRS. One case series also reported the HEAD<sup>5</sup> assessment. Across the studies, follow-up ranged from 12 months to 54 months in the longest study.</p> <p><b>At approximately 12 months follow-up</b></p> <ul style="list-style-type: none"> <li>One NMA (Kondapavulur et al 2023) reported that the weighted mean difference in the absolute reduction in FTM TRS A+B scores between MRgFUS and GK SRS was 1.31 (95% CI -2.96 to 5.99). This was calculated as an indirect comparison between the pooled aggregate of 3 GK SRS studies' (n=62) mean reduction in A+B scores (-10.26, 95% CI<sup>6</sup> -14.21 to -5.96) and the pooled aggregate of 15 MRgFUS studies' (n=464) mean reduction in A+B scores (-11.57 (95% CI -13.3 to -9.93). The NMA results indicated a 72.8% probability that MRgFUS is the more efficacious treatment for tremor reduction, compared with GK SRS. <b>(VERY LOW)</b></li> <li>The systematic review that underpinned the NMA (Kondapavulur et al 2023) also reported the pooled scores at baseline and 12-month follow-up for the GK SRS and MRgFUS studies separately (with no formal indirect comparison). The pooled mean FTM TRS A+B score (mean±SD) at baseline was 20.2±5.6 in the 3 GK SRS studies (n=62), improving to 9.0±8.7 at an average of 14.1 months follow-up. This represented an absolute tremor reduction of -11.41 (95% CI -17.39 to -5.44; I<sup>2</sup>=84%) and a relative tremor reduction of 56.5%. In the 15 pooled MRgFUS studies (n=464), the baseline score of 18.3±5.2 improved to 7.3±5.7 at approximately 10.3 months follow-up. This represented an absolute tremor reduction of -11.13 (95% CI -12.74 to -9.52; I<sup>2</sup>=79%) and a relative tremor reduction of 60.8%. <b>(VERY LOW)</b></li> <li>One case series (Tuleasca et al 2018) reported the percentage of overall improvement in FTM TRS at 12 months for 52 people with medication-refractory ET treated with unilateral GK SRS. The mean±SD (range) improvement was 67.8%±32.9% (range 0 to 100%). <b>(VERY LOW)</b></li> <li>One case series (Witjas et al 2015) reported that: <ul style="list-style-type: none"> <li>the median (IQR) FTM TRS global tremor score (unblinded assessment) improved <i>statistically significantly</i> from baseline by 63.40% (38.3 to 90.6); p&lt;0.0001 between baseline and 12 months for 50 people (36 with ET and 14 with PD). <b>(VERY LOW)</b></li> <li>the median (IQR) FTM TRS upper limb tremor score (blinded assessment) improved <i>statistically significantly</i> from baseline by 54.2% (36.2 to 79.2); p&lt;0.0001 between baseline and 12 months for 50 people (36 with ET and 14 with PD). <b>(VERY LOW)</b></li> </ul> </li> <li>One case series (Bolton et al 2022) reported a <i>statistically significant</i> average improvement from baseline in HEAD score for 34 people with medication-refractory ET 12 months after unilateral GK SRS. The mean±SD (range) pre-treatment scores of 1±0.85 (0 to 2) improved to 0.56±0.75 (0 to</li> </ul> |

<sup>3</sup> Three retrospective case series, one prospective case series and one case series where it was not clear from the text whether this was a prospective or retrospective case series.

<sup>4</sup> FTM TRS is a 21-item scale, of which 9 items relate to tremor and three to drawing (A, B, C). Each item's score has a possible range of 0 to 4.

<sup>5</sup> Bolton et al 2022 describe the HEAD score as an assessment of head tremor on the Tremor Research Group Essential Tremor Rating Assessment. Possible scores range from 0 to 3, with benefit indicated by a lower score.

<sup>6</sup> Although Figure 2 in Kondapavulur et al 2023 appears to report credible intervals rather than confidence intervals, the main text of the paper describes confidence intervals, which would be consistent with their frequentist approach rather than a Bayesian analysis, so the data have been reported here as confidence intervals.

| Outcome | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
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|         | <p>3), representing an average change of <math>-0.39 \pm 0.83</math> (-2 to 1); <math>p=0.035</math>. <b>(VERY LOW)</b></p> <p><b>At approximately 28 months follow-up</b></p> <ul style="list-style-type: none"> <li>One case series (Horisawa et al 2023) reported subscales of the FTM CRS at a mean<math>\pm</math>SD follow-up of <math>28.3 \pm 17.6</math> months for 27 people with ET<sup>7</sup>:             <ul style="list-style-type: none"> <li>a <i>statistically significant</i> improvement from baseline in FTM tremor score from <math>3.4 \pm 0.6</math> before treatment to <math>1.5 \pm 1.2</math> after unilateral GK SRS (55.9% improvement; <math>p&lt;0.001</math>). <b>(VERY LOW)</b></li> <li>a <i>statistically significant</i> improvement from baseline in FTM writing score from <math>3.3 \pm 1.0</math> before treatment to <math>1.4 \pm 1.1</math> after unilateral GK SRS (57.6% improvement; <math>p&lt;0.001</math>). <b>(VERY LOW)</b></li> <li>a <i>statistically significant</i> improvement from baseline in FTM spiral drawing score from <math>3.2 \pm 0.8</math> before treatment to <math>1.6 \pm 1.3</math> after unilateral GK SRS (50% improvement; <math>p&lt;0.001</math>). <b>(VERY LOW)</b></li> </ul> </li> <li>One case series (Niranjan et al 2017, <math>n=73/91</math>)<sup>8</sup> reported:             <ul style="list-style-type: none"> <li>a <i>statistically significant</i> improvement from baseline in FTM TRS tremor score with a mean<math>\pm</math>SD score of <math>3.19 \pm 0.74</math> pre-treatment improving to <math>1.23 \pm 1.01</math>; <math>p&lt;0.0001</math>. <b>(VERY LOW)</b></li> <li>a <i>statistically significant</i> improvement from baseline in FTM TRS writing score with a mean<math>\pm</math>SD score of <math>2.97 \pm 0.75</math> pre-treatment improving to <math>1.25 \pm 1.09</math>; <math>p&lt;0.0001</math>. <b>(VERY LOW)</b></li> <li>a <i>statistically significant</i> improvement from baseline in FTM TRS drawing score with a mean<math>\pm</math>SD score of <math>3.16 \pm 0.67</math> pre-treatment improving to <math>1.26 \pm 1.12</math>; <math>p&lt;0.0001</math>. <b>(VERY LOW)</b></li> <li>a <i>statistically significant</i> improvement from baseline in FTM TRS drinking score with a mean<math>\pm</math>SD score of <math>3.14 \pm 0.67</math> pre-treatment improving to <math>1.36 \pm 1.21</math>; <math>p&lt;0.0001</math>. <b>(VERY LOW)</b></li> </ul> </li> <li>One case series (Niranjan et al 2017, <math>n=73</math>) also reported a summary of the improvements in FTM TRS score:             <ul style="list-style-type: none"> <li>68 (93.2%) experienced improvement in at least 1 FTM score</li> <li>57 (72.2%) improved in all 4 FTM scores</li> <li>3 (3.7%) improved in 3 FTM scores</li> <li>6 (7.6%) improved in 2 FTM scores</li> <li>2 (2.5) improved in 1 FTM score</li> <li>11 (13.8%) did not improve in any FTM score</li> <li>68 (93.2%) experienced improvement in tremor</li> <li>67 (91.8%) noted functional improvement (writing, drawing, drinking from a cup) for the treated arm, of whom:                 <ul style="list-style-type: none"> <li>25 (34.2%) had excellent functional improvement (a reduction of <math>\geq 3</math> levels or a score of 0)</li> <li>59 (80.8%) had good or better (a reduction of 1 to <math>&lt;3</math> levels)</li> <li>67 (91.8%) had satisfactory or better improvement (<math>&lt;1</math> level)</li> </ul> </li> <li>18 (24.7%) experienced tremor arrest or complete recovery of function, with median time to tremor arrest of 4 months (range 2 weeks to 12 months). <b>(VERY LOW)</b></li> </ul> <p><b>At approximately 54 months follow-up</b></p> <ul style="list-style-type: none"> <li>One case series (Niranjan et al 2017) had longer-term follow-up for a subset of 28/91 patients followed up for <math>&gt; 3</math> years (median 54 months, range 37 to 152) and reported:</li> </ul> </li></ul> |

<sup>7</sup> Horisawa et al 2023 did not state clearly that people were medication refractory, but this was implied in the text.

<sup>8</sup> The length of follow-up in the Niranjan et al 2017 paper is ambiguous. The text states that clinical and imaging follow follow-up was collected 4 to 6 months post-GK SRS, but also mentions that median time to last follow-up was 28 months (range 6 to 152).

| Outcome                                                                                | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
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|                                                                                        | <ul style="list-style-type: none"> <li>○ a <i>statistically significant</i> improvement from baseline in FTM TRS tremor score with a mean score<sup>9</sup> of 3.1 pre-treatment improving to 1.0 at approximately 54 months; <math>p &lt; 0.01</math>. <b>(VERY LOW)</b></li> <li>○ a <i>statistically significant</i> improvement from baseline in FTM TRS writing score with a mean score of 2.85 pre-treatment improving to 0.96 at approximately 54 months; <math>p &lt; 0.001</math>. <b>(VERY LOW)</b></li> <li>○ a <i>statistically significant</i> improvement from baseline in FTM TRS drawing score with a mean score of 2.96 pre-treatment improving to 0.79 at approximately 54 months; <math>p &lt; 0.001</math>. <b>(VERY LOW)</b></li> <li>○ a <i>statistically significant</i> improvement from baseline in FTM TRS drinking score with a mean score of 3.11 pre-treatment improving to 1.04 at approximately 54 months; <math>p &lt; 0.001</math>. <b>(VERY LOW)</b></li> </ul> <ul style="list-style-type: none"> <li>• One case series (Niranjan et al 2017) also reported a summary of the improvements in FTM TRS score for a subset of 28/91 patients followed up for &gt; 3 years (median 54 months, range 37 to 152):             <ul style="list-style-type: none"> <li>○ 2/28 (28.57%) had complete resolution of tremor</li> <li>○ 12/28 (42.8%) had an excellent outcome for tremor (tremor score of 1)</li> <li>○ 8/28 (28.57%) had good outcome tremor control (tremor score of 2). <b>(VERY LOW)</b></li> </ul> </li> </ul> <p>One NMA provided very low certainty evidence that the improvement seen in FTM TRS A+B scores for people with ET who underwent GK SRS was 1.31 points (95% CI -2.96 to 5.99) less than the improvement seen for people with ET who underwent MRgFUS, with a 73% probability that MRgFUS was the more efficacious treatment.</p> <p><b>Four studies also provided very low certainty non-comparative evidence that people with medication refractory ET who underwent unilateral GK SRS experienced <i>statistically significant</i> improvements from baseline in tremor, writing, drawing, and drinking scores, and one other study reported the percentage of overall improvement without reporting statistical significance. Follow-up times ranged from 12 to 54 months. At 12 months, <i>statistically significant</i> improvements from baseline in tremor of between 57% and 68% were reported for people with medication refractory ET (and <i>statistically significant</i> improvements from baseline of 54% to 63% in a study of people with either ET or PD). A <i>statistically significant</i> improvement from baseline of 56% was reported at 28 months. Improvements in tremor at a median of 28 months were in the region of 1.25 points (where the scale's possible score range from 0 to 4), with improvements in tremor being experienced by 93% of people. At the longest follow-up (&gt; 3 years), 29% had complete resolution of tremor, 43% had an excellent outcome, and 29% had a good outcome for tremor control.</b></p> |
| <b>Activities of daily living</b><br><br><b>Certainty of evidence:</b><br><br>Very low | <p>ADLs are important outcomes to patients as they facilitate enablement and independence, allowing individuals to function in education, work, home, and recreational settings. They encompass patients' individual needs and facilitate inclusion and participation.</p> <p>In total, two case series<sup>10</sup> reported activities of daily living at approximately 12 months after unilateral GK SRS radiosurgery for people with medication-resistant ET. Both studies used the Bain questionnaire<sup>11</sup> to assess activities of daily living.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

<sup>9</sup> Niranjan et al 2017 did not present SD for the long-term data.

<sup>10</sup> One prospective case series and one case series where it was not clear from the text whether this was a prospective or retrospective case series.

<sup>11</sup> The Bain self-reported questionnaire has 25 items, and each is scored from 1 (able to do the activity without difficulty) to 4 (cannot do the activity); benefit is indicated by a lower score.

| Outcome                                                                                      | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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|                                                                                              | <p><b>At approximately 12 months follow-up</b></p> <ul style="list-style-type: none"> <li>One case series (Bolton et al 2022) reported a <i>statistically significant</i> improvement from baseline in Bain score at 12 months after unilateral GK SRS for 34 people with medication-refractory ET. The mean±SD (range) pre-treatment scores of 29.59±11.39 (13 to 49) reduced to 6.03±11.26 (0 to 41), representing an average change (improvement) of -23.56±12.35 points (-48 to 2); p&lt;0.0001. <b>(VERY LOW)</b></li> <li>One case series (Witjas et al 2015) reported that the mean<sup>12</sup> improvement in Bain score from baseline to 12 months follow-up was 72.2% (range 0% to 100%) but reported no statistical tests or any further data. This study included 50 people, 36 with ET and 14 with PD. <b>(VERY LOW)</b></li> </ul> <p><b>These studies provided very low certainty evidence of an improvement in activities of daily living for people with medication-refractory ET at approximately 12 months after unilateral GK SRS. A statistically significant improvement from baseline of approximately 24 points on the Bain questionnaire was reported by one study, and another study reported an improvement of 72% on the Bain questionnaire scores but did not report on statistical significance.</b></p>                               |
| <b>Important outcomes</b>                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <p><b>Symptom recurrence</b></p> <p><b>Certainty of evidence:</b></p> <p>Very low</p>        | <p>This is important to patients as the aim of treatment would be to reduce their essential tremor symptom burden and avoid further interventions of treatments.</p> <p>In total, one retrospective case series presented non-comparative results for symptom recurrence at a median time of 28 months after unilateral GK SRS for 73<sup>13</sup> people with medication-refractory ET, and longer follow-up of three or more years for 28 people with medication-refractory ET.</p> <p><b>At approximately 28 months follow-up</b></p> <ul style="list-style-type: none"> <li>One case series (Niranjan et al 2017) reported that 7 (9.6%) of 73 patients had symptom recurrence within a median of 28-months follow-up. <b>(VERY LOW)</b></li> </ul> <p><b>At approximately 54 months follow-up</b></p> <ul style="list-style-type: none"> <li>One case series (Niranjan et al 2017) reported that 3 (10.7%) of 28 patients followed-up for more than three years had symptom recurrence within a median of 54-months follow-up. <b>(VERY LOW)</b></li> </ul> <p><b>One study provided very low certainty non-comparative evidence that the rate of symptom recurrence after unilateral GK SRS for people with medication-refractory ET was approximately 10% at a median of 28 months follow-up and approximately 11% at a longer follow-up of 54 months.</b></p> |
| <p><b>Intraoperative pain</b></p> <p><b>Certainty of evidence:</b></p> <p>Not applicable</p> | <p>This is important for patients as if a procedure is more likely to be comfortable and pain-free, they may take this into consideration when making autonomous decisions about their treatment.</p> <p><b>No evidence was identified for this outcome.</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>Length of hospital stay</b></p> <p><b>Certainty of evidence:</b></p>                   | <p>This is important to patients as a shorter hospital admission or stay will have a less disruptive impact on their lives.</p> <p><b>No evidence was identified for this outcome.</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

<sup>12</sup> Although the Methods text in Witjas et al 2015 states that results are median (IQR), the result “72.2% (0% to 100%)” is stated to be the mean improvement.

<sup>13</sup> Niranjan et al 2015 analysed data from 73 people who had at least 6 months follow-up out of a total of 91 treated people.

| Outcome                                                             | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
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| Not applicable                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Safety</b>                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Adverse effects</b><br><b>Certainty of evidence:</b><br>Very low | <p>These outcomes are important to patients because they will impact on their treatment choices and recovery and could have long term sequelae if they are irreversible. They reflect the tolerability and adverse effects of the treatment. From a service delivery perspective, they reflect the additional demands placed on the health system to manage the adverse consequences of the treatment.</p> <p>In total, one systematic review and two retrospective case series reported adverse events experienced by people with medication-refractory ET at between one year and 152 months following unilateral GK SRS.</p> <p><b>At 12 months follow-up</b></p> <ul style="list-style-type: none"> <li>One case series (Tuleasca et al 2018) reported that 0 of 52 patients with ET experienced any side effects within a year of unilateral GK SRS. (<b>VERY LOW</b>)</li> </ul> <p><b>At approximately 28 months follow-up</b></p> <ul style="list-style-type: none"> <li>One case series (Horisawa et al 2023) reported that 21 of 27 people with ET<sup>14</sup> (77.8%) had no adverse events at a mean±SD follow-up of 28.3±17.6 months, and that 6 (22.2%) had at least one adverse event (some patients had &gt;1). The following were reported:               <ul style="list-style-type: none"> <li>Dysarthria: 2 (7.4%)</li> <li>Dysphagia: 1 (3.7%)</li> <li>Lip numbness: 3 (11.1%)</li> <li>Finger numbness: 3 (11.1%)</li> <li>Complete hemiparesis: 2 (7.4%)</li> <li>Foot weakness: 1 (3.7%)</li> <li>Death: 1 (3.7%). (<b>VERY LOW</b>)</li> </ul> </li> </ul> <p><b>At approximately 11 to 152 months follow-up</b></p> <ul style="list-style-type: none"> <li>One systematic review (Kondapavulur et al 2023) reported pooled adverse event data from 11 GK SRS studies (n=449) but did not present any statistical analysis<sup>15</sup>:               <ul style="list-style-type: none"> <li>Imbalance/gait disturbance: 0 (0%)</li> <li>Sensory disturbance: 5 (1.1%)</li> <li>Dysmetria: 0 (0%)</li> <li>Dysgeusia: 0 (0%)</li> <li>Motor weakness: 12 (2.7%)</li> <li>Dysarthria: 11 (2.4%)</li> <li>Other: 3 (0.7%). (<b>VERY LOW</b>)</li> </ul> </li> </ul> <p><b>These studies provide very low certainty non-comparative evidence that the overall rate of adverse effects ranged from 0 at 12 months to 22% at 28 months. The most commonly reported adverse effects among people with ET who had unilateral GK SRS included lip numbness (11%), finger numbness (11%), dysarthria (7%) and complete hemiparesis (7%). Pooled data from 11 studies found that, at between 11- and 152-months follow-up, the most commonly reported adverse effects were motor weakness (2.7%) and dysarthria (2.4%)</b></p> |
| <b>Abbreviations</b>                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

<sup>14</sup> Horisawa et al 2023 did not state clearly that people were medication refractory, but this was implied in the text.

<sup>15</sup> There was no direct evidence for GK SRS vs FUS-T. Indirect evidence for efficacy was included in the NMA, but Kondapavulur et al 2023 did not undertake a formal indirect comparison for AE and only reported data for individual studies, none of which compared FUS-T vs GK SRS data.

| Outcome | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         | ADL: activities of daily living; CI: confidence interval; ET: essential tremor; FTM CRS: Fahn-Tolosa-Marin Clinical Rating Scale; FTM-TRS: Fahn-Tolosa-Marin Tremor Rating Scale; GK SRS: gamma knife stereotactic radiosurgery; HEAD: Tremor Research Group Essential Tremor Rating Assessment; IQR: interquartile range; MRgFUS: magnetic resonance-guided focused ultrasound; NMA: network meta-analysis; PD: Parkinson's disease; QUEST: quality of life in essential tremor |

## In people with medication refractory essential tremor, what is the cost effectiveness of gamma knife SRS compared with current standard care?

| Outcome                             | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Cost of GK SRS in 2016 USD</b>   | <p>One study (McClelland et al 2017) examined the cost of GK SRS compared with DBS<sup>16</sup> from a US perspective, with costs reported in 2016 USD. The study included costs for people with medication-refractory tremor, but this was not specified to be ET. The study did not include any effectiveness data, and costs were based on 2016 Medicare Ambulatory Payment Classification costs for GK SRS and the RVU code, multiplied by a conversion factor of \$37.942<sup>17</sup> per RVU to obtain the neurosurgeon cost for VIM radiosurgery.</p> <ul style="list-style-type: none"> <li>The total cost of GK SRS was \$10,811.77 per patient</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Cost-effectiveness of GK SRS</b> | <p>One study (Ravikumar et al 2017) examined the cost effectiveness of GK SRS compared with MRgFUS for people with ET. The study used a US provider perspective and reported costs in 2016 USD. The time period of the model is based on one-year effectiveness data.</p> <ul style="list-style-type: none"> <li>Effectiveness<sup>18</sup>, mean<math>\pm</math>SD<br/> GK SRS: 0.116<math>\pm</math>0.003<br/> MRgFUS: 0.194<math>\pm</math>0.005<br/> Difference: p&lt;0.001</li> <li>Cost (2016 USD)<br/> GK SRS: \$20,013<math>\pm</math>\$1036<br/> MRgFUS: \$20,593<math>\pm</math>\$1402<br/> Difference: p=0.654</li> </ul> <p>The base case result showed that MRgFUS is more costly than GK SRS but more effective. The authors concluded that MRgFUS is cost-effective for tremor compared with GK SRS but noted that if the effectiveness of MRgFUS were found to be less than initially measured (or the cost greater), GK SRS may be the more cost-effective procedure. The authors estimated the cost of MRgFUS based on the cost of GK SRS with some additional reimbursement for the MRI scan and intraoperative mapping. They acknowledge that this may be an underestimate of the actual cost.</p> <p><b>Cost effectiveness is an important outcome for decision makers, although it may not be a priority to individual patients. Limitations of the two economic evaluations included here are that the US perspective may not be generalisable to the UK, one study only reported costs with no indication of cost-effectiveness (i.e. no consideration of treatment effects), and the short time horizon used by the only study to have developed a cost-effectiveness model. In addition, the cost-effectiveness study only</b></p> |

<sup>16</sup> DBS results not reported here, as not within scope.

<sup>17</sup> The conversion factor used by McClelland et al 2017 was taken from their earlier publication on Parkinson's Disease.

<sup>18</sup> Ravikumar et al 2017: Effectiveness measured by amount of utility added by the procedure. The higher the number, the more effective. It is not clear what the  $\pm$  figures are in the published paper. Assumed to be standard deviations.

| Outcome                                                                                                                                                                                                                                                                                                                 | Evidence statement                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                         | reported the costs and effectiveness of the two modelled treatments separately, with no ICER or cost per QALY reported for the comparison between GK SRS and MRgFUS, although these were reported for the comparison between DBS and GK SRS. |
| <b>Abbreviations</b><br>DBS: deep brain stimulation; ET: essential tremor; GK SRS: gamma knife stereotactic radiosurgery; ICER: incremental cost effectiveness ratio; QALY: quality-adjusted life year; RVU: relative value unit; SD: standard deviation; USD: United States dollars; VIM: ventral intermediate nucleus |                                                                                                                                                                                                                                              |

**From the evidence selected, are there any subgroups of patients that may benefit from gamma knife SRS more than the wider population of interest?**

| Subgroup                                                                                                      | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>People with previous DBS</b>                                                                               | <p>One case series (Witjas et al 2015) reported subgroup results for one person with ET<sup>19</sup> who underwent unilateral GK SRS having previously been treated with DBS, with a follow-up time of 12 months.</p> <ul style="list-style-type: none"> <li>For the person with previous DBS, tremor score had improved by 45.7% at 12 months.</li> <li>For the person with previous DBS, ADL score improved by 66.7% at 12 months.</li> </ul> <p><b>Although Witjas et al 2015 reported results for a single patient who had had previous DBS, they do not suggest that people with previous DBS might benefit from GK SRS more than the wider population of interest. The improvement in this patient was less than that reported for the overall cohort, where the overall tremor score improvement was 63.4% and the ADL improvement was 72.2%.</b></p>                                                                                                                         |
| <b>Improved patients (with ≥50% improvement in ADL) vs non-improved patients (&lt;50% improvement in ADL)</b> | <p>One case series (Witjas et al 2015) divided patients with ET or PD<sup>20</sup> into 'improved' or 'non-improved' based on their ADL score (50% or more improvement vs &lt;50% improvement, respectively).</p> <p>Improved patients (n=38)</p> <ul style="list-style-type: none"> <li>Median (IQR) ADL improvement at 12 months: 96.4% (87.5% to 100%)</li> <li>Median (IQR) global tremor score at baseline: 17 (14 to 22)</li> <li>Median (IQR) global tremor score improvement at 12 months: 64.9% (50% to 86%)</li> </ul> <p>Non-improved patients (n=12)</p> <ul style="list-style-type: none"> <li>Median (IQR) ADL improvement: 0% (5.9% to 15.2%)<sup>21</sup></li> <li>Median (IQR) global tremor score at baseline: 21 (14.8 to 25)</li> <li>Median (IQR) global tremor score improvement: NR</li> </ul> <p><b>Although Witjas et al 2015 analysed improved vs non-improved patients, it is unclear what the clinical characteristics of these patients are and</b></p> |

<sup>19</sup> Witjas et al 2015 report previous DBS separately for people with ET and people with PD, so only the ET results are reported here.

<sup>20</sup> Witjas et al 2015 did not report results separately for the 36 patients with ET but did note that "Neither the tremor etiology (PD or ET) nor the tremor score severity influenced the outcome".

<sup>21</sup> Witjas et al 2015 describe this as "12 were nonimproved (median ADL improvement 0% [5.9%–15.2%])." From elsewhere in the text, the range in brackets is assumed to be the IQR, but it is not clear why this does not include the median value of 0%.

| Subgroup                                                                                                                                                                                                        | Evidence statement                                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                 | therefore it is not possible to identify a subgroup of patients that may benefit from GK-SRS from this data. |
| <b>Abbreviations</b><br>ADL: activities of daily living; DBS: deep brain stimulation; ET: essential tremor; GK SRS: gamma knife stereotactic radiosurgery; IQR: interquartile range; n=number; NR: not reported |                                                                                                              |

**From the evidence selected, what was the treatment dose of gamma knife SRS in the population of interest?**

| Outcome                                                                                                      | Evidence statement                                                                                                                                                                                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Treatment dose of GK SRS</b>                                                                              | <p>In four case series, a maximum dose of 130 Gy was delivered (Bolton et al 2022, Horisawa et al 2023, Tuleasca et al 2018, Witjas et al 2015).</p> <p>The case series by Niranjana et al 2017 describes giving a median central dose of 140 Gy (range 130 to 150).</p> <p>The systematic review and NMA by Kondapavuluri et al 2023 does not describe the doses used in the included studies.</p> |
| <b>Abbreviations</b><br>GK SRS: gamma knife stereotactic radio surgery; Gy: gray; NMA: network meta-analysis |                                                                                                                                                                                                                                                                                                                                                                                                     |

## Patient Impact assessment

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>The condition has the following impacts on the patient's everyday life:</b></p> <ul style="list-style-type: none"> <li>• <b>mobility:</b> Patients have severe problems in walking about</li> <li>• <b>ability to provide self-care:</b> Patients have severe problems in washing or dressing</li> <li>• <b>undertaking usual activities:</b> Patients are unable to do their daily activities</li> <li>• <b>experience of pain/discomfort:</b> Patients have moderate pain or discomfort</li> <li>• <b>experience of anxiety/depression:</b> Patients are extremely anxious or depressed</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <p><b>Further details of impact upon patients:</b></p> <p>The consequences of essential tremor negatively impact on patients' ability to function independently. As the tremor increases in severity, it can become disabling in the home and workplace, interfering significantly in quality of life, functional activities, mood and socialising, often leaving the patient reclusive and dependent on others. The more severe essential tremor may leave patients completely unable to use cutlery or glassware without spilling the contents, and writing may be impossible. There is also a negative psychosocial effect, including social fear and embarrassment, further impacting on quality of life and leading to isolation.</p> <p><b>Further details of impact upon carers:</b></p> <p>The impact on carers can be variable. Some carers are required to support nearly all aspect of patient's life, especially around activities that rely on fine motor function such as writing, cooking and eating. The caring role can be full time and thus impacts on the</p> |

carer's social and work life. Carers can also experience similar psychosocial effects as patients.

## Considerations

| Equality and Health Inequalities Impact Assessment (EHIA) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Summary of any potential impacts of the proposal          | <p>Essential tremor can occur at all ages although it is significantly more common as people get older. There is no known difference in prevalence of essential tremor in people from different ethnicities and there is no link with deprivation.</p> <p>This intervention may be of particular benefit for many members of protected characteristic groups and other groups who face health inequalities as it is less invasive and can be performed as a day case. However, it is acknowledged people from these groups may also find travelling to a specialist centre to receive this treatment a barrier.</p> <p>NHS England has recently increased the number of all-tiers SRS services from 2 to 4 improving geographical access to SRS for patients.</p> |
| 13Q Assessment                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| PPVAG outcome                                             | No consultation required                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Were PPVAG assured of the level of stakeholder testing?   | PPVAG were fully assured.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Rare Disease Advisory Group                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Not Applicable                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Pharmaceutical                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Not Applicable                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |



## National Programme of Care

The proposal received the full support of the Cancer National Programme of Care Assurance Group.