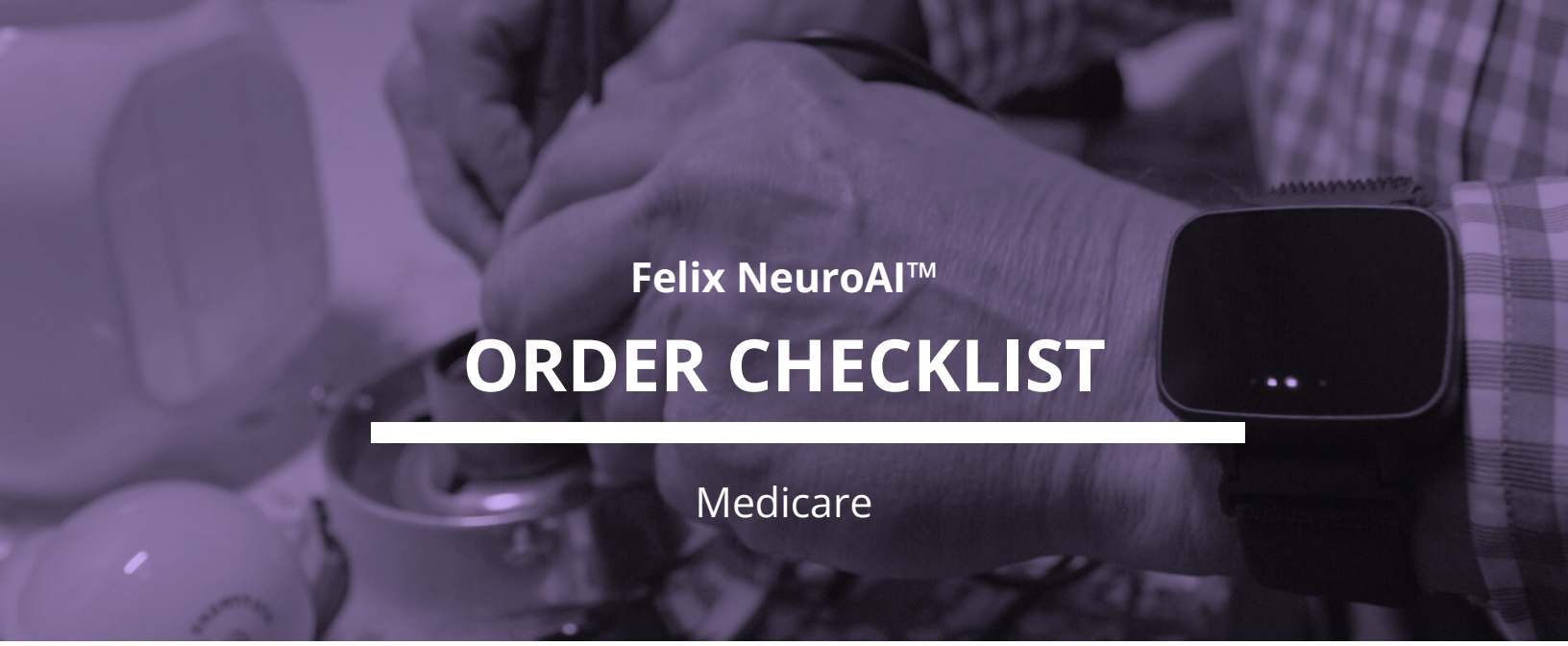

Felix NeuroAI™

ORDER CHECKLIST

Medicare

To submit a prescription, please follow these steps:

1. Verify that **ALL** the Medicare criteria are met for Medicare coverage (page 1 to 3) and **document every criterion in the medical record** according to the Medical Record Guidance.*

2. Complete the Standard Written Order (SWO) (Page 4).

3. Sign the Bain and Findley Assessment document and upload it to the patient's medical record.

4. Send the SWO, Bain and Findley Assessment, and ALL relevant Medical Records to

Fax: 800-673-3999

* **NOTE**: If the patient does not meet the Medicare criteria but wants to pay for Felix out-of-pocket, please switch to the Non-Medicare prescription found at https://fasikl.com/providers.

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Medicare Local Coverage Determination (LCD) for External Upper Limb Tremor Stimulator

INITIAL COVERAGE

An external upper limb tremor stimulator of the peripheral nerves of the wrist (E0734) is covered when the beneficiary has had a clinical evaluation (in-person or via Medicare-approved telehealth) ***pertaining to the prescription of the device*** by the treating practitioner, and ALL of the following criteria are met AND documented in the medical record. ***There must be information in the beneficiary's medical record that supports the following medical criteria.*** **Please fax the medical record to 800-673-3999.**

Criteria	Description	Medical Record Guidance
1.	The beneficiary has a diagnosis of essential tremor (ET), ICD-10 code G25.000; and	ET diagnosis
2.	The beneficiary is 18 years or older; and	Patient's date of birth and/or age
3.	The beneficiary has no contraindications to external upper limb tremor stimulator therapy ***(Suspected or confirmed epilepsy; pregnancy; implanted electrical device such as a pacemaker, defibrillator or deep brain stimulator; wrist skin that is swollen, infected, inflamed or presents with eruptions, open wounds or cancerous lesions);*** and	A statement including: 1. The contraindications have been discussed with the patient, and 2. Confirmation that the patient does not have any suspected or confirmed contraindications to external upper limb tremor stimulator therapy
4.	The external upper limb tremor stimulator is being prescribed to treat the beneficiary's dominant upper limb; and	Document the patient's dominant upper limb and indicate that Felix NeuroAI™ Wristband is being prescribed to treat the patient's dominant upper limb
5.	The severity of ET symptoms significantly impairs the beneficiary's ability to perform dominant hand, upper limb-related activities of daily living (ADLs) as indicated by a score of greater than or equal to 3 on the Bain & Findley Tremor ADL Scale (BF-ADL) for at least one (1) assessment item for eating, drinking, self-care, or writing); and	A summary of BF-ADL findings focusing on items for eating, drinking, self-care, or writing and whether at least one of those items has a score of 3 or higher. AND Signed BF-ADL form (Refer to the attached BF-ADL form)
6.	If medically appropriate, tremor exacerbating medications (e.g., stimulants, beta agonists) have been reduced or eliminated; and	A statement that the patient is not on tremor exacerbating medications (if applicable) or a statement that tremor exacerbating medication(s) have been reduced or eliminated. If the latter, include the details of the medication(s) and the action taken.
7.	At least two (2) pharmacological treatment options for the management of ET symptoms have been either tried and failed at maximal tolerable treatment dosages (i.e., no or limited effect, intolerable side	Identify at least two medications and the corresponding maximal tolerable treatment dosages. Provide medical records such as prescriptions to support these. Describe how those treatments were attempted at

	effects) or considered and ruled out (e.g., not appropriate in the context of the beneficiary's medical history); and	those doses and why they failed (e.g., timeline, lack of effectiveness, or intolerable side effects). Alternatively, describe the reason(s) why those treatments were considered and ruled out from a medical perspective (e.g., pregnancy, age, comorbidities, contraindications). NOTE: patient preference is NOT SUFFICIENT.
8.	External upper limb tremor stimulator therapy is being prescribed as an alternative to invasive and/or permanent surgical treatment options (e.g., deep brain stimulation, magnetic resonance guided focused ultrasound, radiosurgery).	A statement that invasive and/or permanent surgical treatment options have been considered and that the Felix NeuroAI™ Wristband is being prescribed as an alternative.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY

Continued coverage of external upper limb tremor stimulator therapy, and related supplies and accessories (E0734 and A4542) beyond the first three (3) months of therapy requires that no sooner than the 60th day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation (in-person or via Medicare-approved telehealth) and document that the following criteria are met. ***There must be information in the beneficiary's medical record that supports the following medical criteria.*** **Please fax the medical record to 800-673-3999.**

Criteria	Description	Medical Record Guidance
1.	Deriving benefit from external upper limb tremor stimulator therapy as indicated by a 1- point improvement in BF-ADL score in any eating, drinking, self-care, or writing task scored as greater than or equal to 3 prior to the initiation of therapy; and	A summary of BF-ADL findings focusing on items for eating, drinking, self-care, or writing which had a score of 3 or higher in the initial visit, and whether at least one of those items had a 1-point improvement. AND Signed BF-ADL form (Refer to the attached BF-ADL form)
2.	Adhering to external upper limb tremor stimulator therapy (adherence is defined as use of external upper limb tremor stimulator therapy on 70% of the days during a consecutive thirty (30) day period anytime during the first three (3) months of initial use).	A statement that the patient used the Felix NeuroAI™ Wristband on 70% of the days during a consecutive thirty-day period during the first three months of initial use.

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Bain & Findley Activities of Daily Living (BF-ADL)

Score	Description
1	Able to do the activity without difficulty
2	Able to do the activity with a little effort
3	Able to do the activity with a lot of effort
4	Cannot do the activity by yourself

Instructions: For each item indicate the number which describes how easy or difficult it is for you to perform the activity.
Note: For initial Medicare coverage, a score of greater than or equal to 3 is required on one of the eating, drinking, self-care, or writing tasks (**bold**), which indicates a significant impairment in the beneficiary's ability to perform dominant hand, upper-limb-related activities of daily living. **For continued coverage beyond the first three months,** a 1-point improvement in any eating, drinking, self-care, or writing tasks initially scored as greater than or equal to 3 will be considered as deriving benefit from the therapy. Medicare Local Coverage Determination (L39591) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDid=39591

Task	Task Description	Initial Score					Continuing Coverage Score			
		1	2	3	4		1	2	3	4
1	**Cut food with a knife and fork**	☐	☐	☐	☐		☐	☐	☐	☐
2	**Use a spoon to drink soup**	☐	☐	☐	☐		☐	☐	☐	☐
3	**Hold a cup of tea**	☐	☐	☐	☐		☐	☐	☐	☐
4	**Pour milk from a bottle or carton**	☐	☐	☐	☐		☐	☐	☐	☐
5	Wash and dry dishes	☐	☐	☐	☐		☐	☐	☐	☐
6	**Brush your teeth**	☐	☐	☐	☐		☐	☐	☐	☐
7	**Use a handkerchief to blow your nose**	☐	☐	☐	☐		☐	☐	☐	☐
8	**Use a bath**	☐	☐	☐	☐		☐	☐	☐	☐
9	**Use the lavatory**	☐	☐	☐	☐		☐	☐	☐	☐
10	**Wash your face and hands**	☐	☐	☐	☐		☐	☐	☐	☐
11	**Tie up your shoelaces**	☐	☐	☐	☐		☐	☐	☐	☐
12	**Do up buttons**	☐	☐	☐	☐		☐	☐	☐	☐
13	**Do up a zip**	☐	☐	☐	☐		☐	☐	☐	☐
14	**Write a letter**	☐	☐	☐	☐		☐	☐	☐	☐
15	Put a letter in an envelope	☐	☐	☐	☐		☐	☐	☐	☐
16	Hold and read a newspaper	☐	☐	☐	☐		☐	☐	☐	☐
17	Dial a telephone	☐	☐	☐	☐		☐	☐	☐	☐
18	Make yourself understood on the Telephone	☐	☐	☐	☐		☐	☐	☐	☐
19	Watch television	☐	☐	☐	☐		☐	☐	☐	☐
20	Pick up your change in a shop	☐	☐	☐	☐		☐	☐	☐	☐
21	Insert an electric plug into a socket	☐	☐	☐	☐		☐	☐	☐	☐
22	Unlock your front door with the key	☐	☐	☐	☐		☐	☐	☐	☐
23	Walk up and down stairs	☐	☐	☐	☐		☐	☐	☐	☐
24	Get up out of an armchair	☐	☐	☐	☐		☐	☐	☐	☐
25	Carry a full shopping bag	☐	☐	☐	☐		☐	☐	☐	☐

Bain PG, Findley LJ, Atchison P, et al. Assessing tremor severity. Journal of Neurology, Neurosurgery & Psychiatry. 1993;56(8):868-73.

Treating Practitioner Signature:
Initial scores reviewed and confirmed by: _____ Date: _____

Continuing coverage scores reviewed and confirmed by: _____ Date: _____
Once signed, please upload this document to the patient's medical records.

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MEDICARE STANDARD WRITTEN ORDER FORM
Felix NeuroAI™ Wristband for Tremor Relief – Prescription Form

Patient Information

Legal First Name:	**Legal Last Name:**	
Medicare Number:	**Date of Birth**:	**Gender:** ☐ Male ☐ Female
Address:		
City:	**State**:	**Zip Code:**
Email:	**Mobile Phone:**	**Home Phone**:

Diagnosis ICD-10 Code

☐ **G25.0:** Essential tremor
☐ Other:

External Upper Limb Tremor Stimulator Description

Felix NeuroAI™ Wristband for Essential Tremor **HCPCS Code**: E0734 **Description**: External upper limb tremor stimulator of the peripheral nerves of the wrist **Quantity:** 1
Felix NeuroAI™ Electrode Bands **HCPCS Code**: A4542 **Description:** Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist **Quantity:** 3 boxes (90-day supply) **Refill frequency**: every 90 days

Local Coverage Determination (LCD) criteria must be met and documented in the patient's medical record for INITIAL COVERAGE and CONTINUED COVERAGE (See attached LCD criteria)

Prescriber Authorization

Treating Practitioner Signature:	**Order Date**:
Treating Practitioner Name:	**NPI #**
Clinic Name:	**Email Address**:
Phone Number:	**Fax Number**:

Please fax the completed form to 800-673-3999.