Pre-Authorization request

For the FDA-cleared Durable Medical Equipment **NightWatch+ (US) Seizure Monitor**
For the purpose of reimbursement (Code E1399)

NightWatch+
Epilepsy Monitoring

The FDA-cleared version of the NightWatch+ for the US is a prescription-only device that is indicated for use as an adjunct to seizure monitoring of children aged 4 to 16 diagnosed with epilepsy having Nocturnal Epileptic Major Motor Seizures, which includes tonic-clonic (TC), tonic (if clustered or prolonged >30 seconds), hyperkinetic and TC-like seizures, in home or residential facilities during periods of rest. The Sensor of the device is worn on the upper arm and measures heart rate and motion data to detect patterns that may be associated with nocturnal epileptic motor seizures in patients with epilepsy. When a seizure event is detected by the Sensor of the NightWatch+ US, it sends a command to the paired wireless alarm station of the NightWatch+ US that is programmed to initiate an alarm to a designated caregiver. The system records and stores data from seizure events. The data can be viewed by the user in a cloud-based data portal. The NightWatch+ US is not intended to diagnose specific seizure types.

TO: *Insurance Carrier / Medical Review Department*

FROM:

Dr.

Practice/Clinic Name

Address

Phone

Fax

NPI Number

Date (MM/DD/YYYY)

PATIENT INFORMATION

Patient Name

Date of Birth

Diagnosis (ICD-10): G40.*** (Epilepsy — specify type)

Insurance ID

MEDICAL NECESSITY STATEMENT

I am the treating specialist for Pediatric Neurology / Neurology for the above-named child, who has a confirmed diagnosis of epilepsy with active nocturnal epilepsy or a risk of nocturnal major motor seizures, which includes tonic-clonic (TC), tonic (if clustered or prolonged >30 seconds), hyperkinetic and TC-like seizures. The patient experiences seizures primarily during sleep, which pose a significant safety risk, including the potential for injury, undetected convulsions, and Sudden Unexpected Death in Epilepsy (SUDEP). The NightWatch+ Seizure Detection System is an FDA-cleared Class II medical device (510(k) cleared) designed to detect clinically relevant nocturnal seizures based on monitoring of heart rate, motion, and body position. The system continuously monitors the patient during sleep and alerts caregivers immediately when a potential major seizure is detected. This enables timely intervention and substantially improves patient safety and quality of life. Given the chronic nature of the patient's condition and the associated seizure-related risks, this device is medically necessary as part of the patient's ongoing epilepsy management plan. The NightWatch+ qualifies as durable medical equipment (DME) intended for repeated, long-term home use. No other available DME product or monitoring device provides the same clinically validated seizure-detection capability.

PRESCRIPTION & EQUIPMENT DETAILS

Prescribed Device

NightWatch+ US Seizure Detection Monitor

Manufacturer

LivAssured BV

510(K) Number

K243199, Physiological Signal Based Seizure Monitoring System

Purchase Date (if applicable)

Length of Need

✓ **Indefinite**

Guarantee

2 years, normal product use time: 5 years

PHYSICIAN CERTIFICATION

I certify that the above information is accurate, that the prescribed equipment is medically necessary for the patient's treatment, and that it will be used under my supervision as part of an established plan of care.

Physician Signature

Date (MM/DD/YYYY)

RECOMMENDED ATTACHMENTS

- Physician's prescription (Rx)
- Patient invoice or proof of purchase
- Product description sheet (FDA 510(k) summary optional)
- Clinical notes or seizure log (if applicable)

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