

NightWare DoD ordering guide

1. **Place a DME consult in AHLTA or MHS Genesis.** Be sure to edit the wording below in the 'Suggested Language' section to fit your patient's clinical situation, and put your name and NPI number at the end of the order.
2. **Print the DME consult order and sign, stamp, and date it.** It is important to write the date in by your signature, even though the date of the consult is at the top. You can print when you create the order or go to the Consult Log in AHLTA and find the consult and print from there.
3. **You need to print out the medical note that describes the need for NightWare.** Usually, the note needs to state that the patient is having frequent disturbing nightmares. If they have tried and failed medications or psychotherapy, make sure to mention that in the note.
4. **Print the "demographics" page in AHLTA.** *Write the patient's FMP and SSN on this form; this is necessary and very important!*
5. **Fax the signed order, demographics page, and medical note to the DME vendor of your choice, Optigen or Sleep Management (Doing Business As Viemed).** OCONUS sites should choose Optigen.

Important Note: NightWare is a FDA-cleared specially provisioned smart watch and phone system that is not available as a downloaded application to a patient's personal watch and phone. Patients are not required by Tricare to fail other nightmare treatments prior to the use of NightWare.

INDICATION:

The NightWare Digital Therapeutic is indicated to provide vibrotactile feedback on an Apple Watch based on an analysis of heart rate and motion during sleep for the temporary reduction of sleep disturbance related to nightmares in adults 22 years or older, who suffer from nightmare disorder or have nightmares from post-traumatic nightmare disorder (PTSD). It is intended for home use.

PATIENT INSTRUCTIONS:

NightWare, including the watch and iPhone, will be sent directly to them by the DME supplier. Instructions for set up and use are in the box, and they can call or email NightWare Inc. directly if needed at 844-44-NIGHT (833-446-4448) or support@NightWare.com.



NIGHTWARE

Phone

1-833-44-Night (toll free)

Email

Info@NightWare.com

Web

NightWare.com

NightWare Prescription Wording Suggestion

At the top of the order, include the name and phone number of the DME company you are sending the patient information to and patient notes.

DME: Sleep Management (dba Viemed)

NPI: 1336166347

Fax 800-358-1907

Sleep Management (dba Viemed) contact number: 833-735-1192

DME: Optigen

NPI: 1578592309

Fax: 877-339-0180

Optigen contact number: 800-273-9114 x13832 or x13800

SUGGESTED PRESCRIPTION LANGUAGE:

DME Provider: **[INSERT PREFERRED DME PROVIDER AND NPI AND FAX NUMBER]**
Please provide one (1) NightWare Digital Therapeutic System. Part #100001. HCPCS Code E1399. Length of Service: 99+ months. **[PHYSICIAN NAME], [PHYSICIAN NPI].**

Patient has chronic PTSD-associated nightmares that interfere with daytime functioning. Patient has failed treatment for this condition with medications and psychotherapy, and is still experiencing frequent disruptive nightmares. **[INSERT PATIENT SPECIFICS REGARDING PREVIOUS THERAPIES USED AND LACK OF ADEQUATE CLINICAL RESPONSE. DETAILS COULD INCLUDE FAILED DRUG THERAPIES, PSYCHOTHERAPIES THAT WERE INEFFECTIVE AND WHAT MEDICATIONS AND TREATMENTS THEY ARE CONTINUING AS WELL AS OVERALL TIME PERIOD WITH LOW TO NO CLINICAL RESPONSE]** The patient's daytime functioning will likely continue to deteriorate without intervention.

SPECIAL NOTE: This device is medically necessary. NightWare is a Class II medical device that delivers the NightWare therapy through a dedicated closed system specially provisioned smart watch and phone. The phone and watch have no capability aside from running NightWare and the ability to call 911 in an emergency. It cannot make calls; it cannot run other applications. This is a single purpose device. Therefore, the requested device does meet TRICARE DME requirements.

NightWare can withstand repeated use, only serves a medical purpose, and is not useful to the individual other than to treat the patient's condition. It has been proven to improve sleep quality. Improved sleep will improve the patient's daytime functioning. As an FDA Class II medical device digital therapeutic, it will provide the appropriate level of performance and quality for the medical condition. NightWare can be used in conjunction with other treatments.

Patient has chronic Nightmare Disorder/PTSD-associated nightmares that interfere with their daytime function. Patient has failed treatment for this condition with medications and psychotherapy, and is still experiencing frequent disruptive nightmares.

The following does not need to be included in the DME consult and is for your information only.

NightWare Safety Information

INDICATION:

The NightWare digital therapeutic is indicated to provide vibrotactile feedback on an Apple Watch based on an analysis of heart rate and motion during sleep for the temporary reduction of sleep disturbance related to nightmares in adults 22 years or older who suffer from nightmare disorder or have nightmares from posttraumatic stress disorder (PTSD). It is intended for home use.

CONTRAINDICATIONS:

- If you have acted out your nightmares (i.e. sleepwalking, violence) do not use NightWare and contact your Healthcare Provider.

WARNINGS:

- NightWare is not a standalone therapy for PTSD. This device should be used in conjunction with prescribed medications for PTSD and other recommended therapies for PTSD-associated nightmares and nightmare disorder, according to relevant consensus guidelines.
- If daytime sleepiness occurs, contact your Healthcare Provider.
- If you feel drowsy, do not drive or operate heavy machinery. Contact your Healthcare Provider.
- If the watch vibrations cause awakenings not associated with your nightmares, contact your Healthcare Provider.
- If nightmares persist, worsen, or recur, contact your Healthcare Provider.

- If skin irritation occurs, discontinue use of the watch and contact your Healthcare Provider.
- Your watch may disturb your bed-partner. Try not to expose your bed-partner to the watch at night.
- Do not wear the watch too tightly, it should feel comfortable and snug, but not tight on your wrist.
- Wear the watch only when you are planning to go to sleep; do not wear it while reading or watching TV in bed as this may trigger false alerts.
- Use the NightWare watch every night.
- Not intended for use by individuals under age 22.
- The long term safety and effectiveness of the NightWare device has not been established.
- The long term effects of the NightWare device use on the sleep architecture have not been established.

PRECAUTIONS:

- Do not drop or crush the smartphone or watch.
- Be sure to charge the smartphone and watch every day.

Please see accompanying Instructions for Use.



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