



Request for Prior Authorization
TASIMELTEON (HETLIOZ®)

FAX Completed Form
To
I (800) 574-2515
Provider Help Desk
I (877) 776-1567

(PLEASE PRINT - ACCURACY IS IMPORTANT)

Form with fields for IA Medicaid Member ID #, Patient name, DOB, Patient address, Provider NPI, Prescriber name, Phone, Prescriber address, Fax, Pharmacy name, Address, Phone, Pharmacy NPI, Pharmacy fax, NDC.

Prior authorization (PA) is required for tasimelteon (HetlioZ®). Requests will be considered when patient has an FDA approved or compendia indication for the requested drug. Payment will be considered under the following conditions:

- 1. Request adheres to all FDA approved labeling for requested drug and indication, including age, dosing, contraindications, warnings and precautions, drug interactions, and use in specific populations; and
2. Patient has a documented diagnosis of:
a. Non-24-Hour Sleep-Wake Disorder (Non-24); and
i. Patient has a documented trial and therapy failure with at least one preferred sedative/hypnotic-non-benzodiazepine agent; and
ii. Patient has a documented trial and therapy failure with ramelteon (Rozerem®); or
b. Sleep disturbances in Smith-Magenis Syndrome (SMS); and
i. Documentation of confirmed deletion 17p11.2 (cytogenic analysis or microarray) or RAI1 gene mutation is provided (attach results); and
ii. Patient has a documented trial and therapy failure with at least one other medication used for sleep disturbances; and
3. Is prescribed by, or in consultation with a physician who specializes in the treatment of sleep disorders; and
4. Will not be used concurrently with other sleep medications.

If criteria for coverage are met, initial requests will be approved for 3 months. Requests for continuation of therapy will be considered under the following conditions:

- 1. Patient's use of tasimelteon (HetlioZ) has been continuous without gaps in treatment; and
2. Documentation patient has experienced a positive clinical response to therapy with tasimelteon (HetlioZ®), such as entrainment, significant increase in nighttime sleep, significant decreases in daytime sleep, and/or nighttime sleep quality.

Non-Preferred

[] HetlioZ [] HetlioZ LQ [] Tasimelteon

Strength Dosage Instructions Quantity Days Supply

Diagnosis: _____

Prescriber Specialty: [] Sleep disorder specialist [] Other (specify): _____

If other, note consultation with sleep disorder specialist: Consultation date: _____

Physician name, specialty & phone: _____

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Will other sleep medications be used concurrently with tasimelteon? Yes No

Non-24-Hour Sleep-Wake Disorder (Non-24)

Treatment failure with a preferred sedative/hypnotic-non-benzodiazepine agent:

Drug name & dose: _____ Trial dates: _____

Reason for failure: _____

Treatment failure with ramelteon (Rozerem®):

Trial dose: _____ Trial dates: _____

Reason for failure: _____

Possible drug interactions/conflicting drug therapies: _____

Smith-Magenis Syndrome (SMS)

Attach documentation of one of the following:

Deletion of 17p11.2 (cytogenic analysis or microarray) RAI1 gene mutation

Treatment failure with at least one medication used for sleep disturbances:

Trial drug name & dose: _____ Trial dates: _____

Reason for failure: _____

Requests for continuation therapy:

Has patient's use of tasimelteon been continuous without gaps in treatment? Yes No

Has patient experienced a positive clinical response with tasimelteon therapy? Yes (describe below) No

Patient improvements with tasimelteon (HetlioZ®) therapy (include description):

Entrainment: _____

Significant increase in nighttime sleep: _____

Significant decrease in daytime sleep: _____

Nighttime sleep quality: _____

Other: _____

Attach lab results and other documentation as necessary.

| | |
|--|--------------------|
| Prescriber signature (Must match prescriber listed above.) | Date of submission |
|--|--------------------|

IMPORTANT NOTE: In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Human Services, that the member continues to be eligible for Medicaid.