Hetlioz™ (tasimelteon) Prior Authorization (with Quantity Limit) Program Summary

OBJECTIVE

The intent of the Hetlioz (tasimelteon) prior authorization criteria is to appropriately select patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies and according to dosing recommended in product labeling. Tasimelteon will be approved for use in totally blind patients (i.e. no light perception) with Non-24-Hour Sleep-Wake Disorder (Non-24), or another FDA approved indication. Requests for tasimelteon will be reviewed when patient-specific documentation is provided.

TARGET DRUGS

Hetlioz™ (tasimelteon)

PROGRAM PRIOR AUTHORIZATION AND QUANTITY LIMIT

Brand (generic)	GPI	Multisource Code	Quantity Limit per day
Hetlioz (tasimelteon)			
20 mg capsule	60250070000130	M, N, O, or Y	1 capsule

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Hetlioz will be approved when ALL of the following are met:

1. ONE of the following:
    a. ALL of the following for Non-24-hour sleep-wake disorder:
        i. The patient is totally blind (i.e. no light perception) **AND**
        ii. The patient has a diagnosis of Non-24-hour sleep-wake disorder **AND**
        iii. The prescriber is a sleep specialist or has consulted with a sleep specialist

    OR

    b. ALL of the following:
        i. The patient has another FDA labeled indication **AND**
        ii. The prescriber is a specialist in the area of the patient's diagnosis or has consulted with a specialist in the area of the patient's diagnosis

    AND
2. The patient does not have any FDA labeled contraindications to therapy with Hetlioz (tasimelteon) **AND**
3. The patient does not have severe hepatic impairment (Child-Pugh Class C) **AND**
4. ONE of the following:
    a. The quantity requested is less than or equal to the program quantity limit **OR**
    b. The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength **OR**
    c. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended

diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of Approval: 12 months

FDA Labeled Contraindications

Agent:	Contraindications:
Hetlioz (tasimelteon)	None