Hetlioz® (tasimelteon tablets)
Hetlioz LQ® (tasimelteon oral suspension)
Effective 08/01/2021

<table>
<thead>
<tr>
<th>Plan</th>
<th>Benefit</th>
<th>Program Type</th>
</tr>
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<tbody>
<tr>
<td>☒ MassHealth</td>
<td>☒ Pharmacy Benefit</td>
<td>☒ Prior Authorization</td>
</tr>
<tr>
<td>☒ Commercial/Exchange</td>
<td>☐ Medical Benefit (NLX)</td>
<td>☐ Quantity Limit</td>
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<td></td>
<td></td>
<td>☐ Step Therapy</td>
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</tbody>
</table>

**Specialty Limitations**
N/A

<table>
<thead>
<tr>
<th>Contact Information</th>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>All Plans</td>
<td>MassHealth</td>
</tr>
<tr>
<td></td>
<td>Phone: 866-814-5506</td>
<td>Phone: 877-433-7643</td>
</tr>
<tr>
<td></td>
<td>Fax: 866-249-6155</td>
<td>Fax: 866-255-7569</td>
</tr>
<tr>
<td>Medical Specialty Medications (NLX)</td>
<td>All Plans</td>
<td>Phone: 844-345-2803</td>
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**Exceptions**
N/A

**Overview**
Hetlioz is an agonist of melatonin receptors which induces sleepiness and influences regulation of circadian rhythms.

**Coverage Guidelines**
Authorization may be reviewed for members new to AllWays Health Partners who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

**Hetlioz**
Authorization may be reviewed for members new to AllWays Health Partners who are currently receiving treatment with the requested medication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

OR
Authorization may be granted for members when ALL the following criteria are met, and documentation is provided:

1. The member meets ONE of the following
   a. The member is at least 18 years old and has a diagnosis of non-24-hour sleep-wake disorder (non-24)
   b. The member is at least 16 and has a diagnosis of nighttime sleep disturbances in Smith-
Magenis Syndrome (SMS)

2. The prescriber is a sleep specialist or is being prescribed in consult with a sleep specialist
3. The member has had at least a one-month trial of timed melatonin administration that resulted in a side effect, allergy, or treatment failure

Hetlioz LQ:

1. The member has a diagnosis of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS)
2. The member is between age 3 years and 15 years old
3. The prescriber is a sleep specialist or is being prescribed in consult with a sleep specialist
4. The member has had at least a one-month trial of timed melatonin administration that resulted in a side effect, allergy, or treatment failure

Continuation of Therapy

Reauthorization will be granted if documentation is submitted indicating a positive response to therapy

Limitations

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Limit</th>
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<tbody>
<tr>
<td>Hetlioz 20mg</td>
<td>30 capsules per 30 days</td>
</tr>
<tr>
<td>Hetlioz LQ</td>
<td>150 mL per 30 days</td>
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<tr>
<td>suspension</td>
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</tbody>
</table>

References

3. Auger RR, Burgess HJ, Emens JS, et al. Clinical practice guideline for the treatment of intrinsic circadian rhythm sleep-wake disorders: advanced sleep-wake phase disorder (ASWPD), delayed sleep-wake phase disorder (DSWPD), non-24-hour sleep-wake rhythm disorder (N24SWD), and irregular sleep-wake rhythm

Review History

09/21/2015: Reviewed P&T Mtg
12/29/2015: Implementation Date
11/27/2017: Reviewed P&T Mtg
11/26/2018: Reviewed P&T Mtg
01/22/2020: Added started and stabilized criteria, added indication of non-24 hour sleep wake disorder, removed Rozerem trial
07/21/2021: Reviewed and Updated July P&T; Added Hetlioz LQ and SMS nighttime sleep disturbances for Hetlioz. Effective 08/01/2021.

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.