Health Alliance™

Pharmacy Drug Policy & Procedure

Policy Name:	Hetlioz (tasimelteon)	Policy #:	2361P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Hetlioz.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Hetlioz under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for 24 hour Sleep-Wake Disorder

1.1 Diagnosis of non-24-hour sleep-wake disorder
1.2 Diagnosis of blindness
1.3 Prescribed by or in consultation with a sleep disorder specialist
1.4 Documented failure, intolerance, or contraindication to zolpidem or zaleplon
1.5 Documented failure, intolerance, or contraindication to Rozerem (ramelteon)
1.6 Coverage of brand Hetlioz requires documented allergic reaction to generic tasimelteon

2. Coverage Criteria for Smith-Magenis Syndrome (SMS)

2.1 Diagnosis of Smith-Magenis Syndrome (SMS)
2.2 Age 3 years or older
- Oral suspension for members 3 – 15 years
- Capsules for members 16 years or older

2.3 Documented failure, intolerance, or contraindication to melatonin
2.4 Coverage of brand Hetlioz requires documented allergic reaction to generic tasimelteon

3. Approval Period

3.1 Initial: 12 months
3.2 Reauthorization: 12 months with documented clinical benefit from therapy

References

1. Hetlioz [Prescribing Information]. Washington, D.C., Vanda Pharmaceuticals, Inc., December 2020.
2. 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 SleepWake Rhythm Disorder (ISWRD). An Update for 2015: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med 2015; 11:1199.
3. Brooks J, Czeisler EL, Fisher MA, et al. Tasimelteon safely and effectively improves sleep in Smith-Magenis syndrome: a double-blind randomized trial followed by an open-label extension. Genet Med.

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DISCLAIMER
This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.