

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class**Anxiolytics and Sedatives/Hypnotics (ASHs)**

- **Hetlioz (Tasimelteon) – revision**

This criteria was recommended for review by an MCO to ensure appropriate and safe utilization

Clinical Criteria Information Included in this Document**Hetlioz capsules**

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References:** clinical publications and sources relevant to this clinical criteria

Hetlioz LQ suspension

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
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Revision Notes

Criteria revised for presentation to the DUR Board

**Anxiolytics and Sedatives/Hypnotics
(ASHs)****Hetlioz (Tasimelteon)
Drugs Requiring Prior Authorization**

Drugs Requiring Prior Authorization	
Label Name	GCN
HETLIOZ 20 MG CAPSULE	36068
HETLIOZ LQ 4 MG/ML SUSPENSION	48937



Anxiolytics and Sedatives/Hypnotics (ASHs)

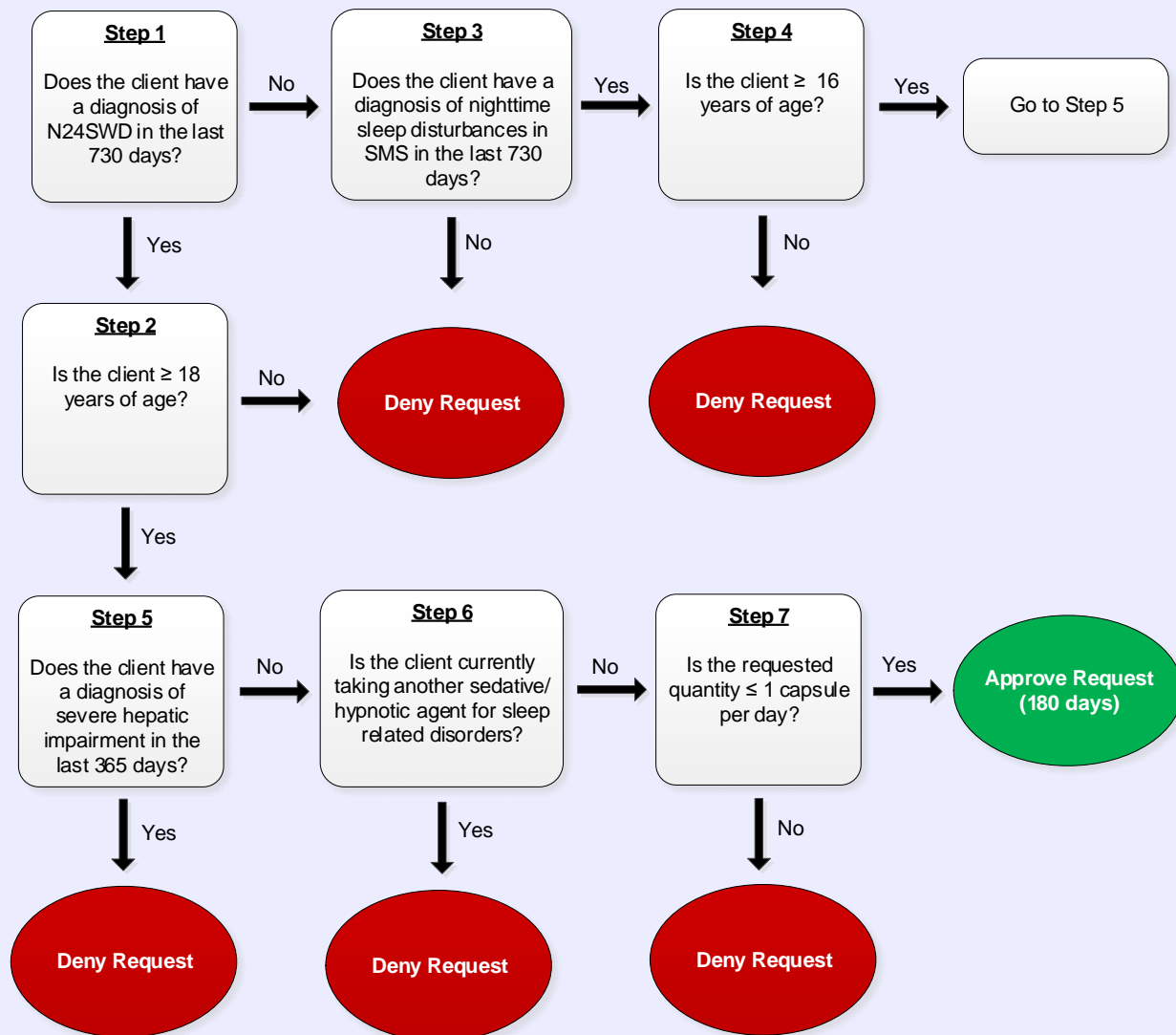
Hetlioz (Tasimelteon) capsules Clinical Criteria Logic

1. Does the client have a diagnosis of **non-24 hour sleep-wake disorder (N24SWD)** in the last 730 days?
 Yes (Go to #2)
 No (Go to #3)
2. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #5)
 No (Deny)
3. Does the client have a diagnosis of nighttime sleep disturbances in **Smith-Magenis Syndrome (SMS)** in the last 730 days?
 Yes (Go to #4)
 No (Deny)
4. Is the client greater than or equal to (\geq) 16 years of age?
 Yes (Go to #5)
 No (Deny)
5. Does the client have a diagnosis of **severe hepatic impairment** in the last 365 days?
 Yes (Deny)
 No (Go to #6)
6. Is the client currently taking another **sedative/hypnotic agent** for sleep related disorders?
 Yes (Deny)
 No (Go to #7)
7. Is the requested quantity less than or equal to (\leq) 1 capsule daily?
 Yes (Approve – 180 days)
 No (Deny)



Anxiolytics and Sedatives/Hypnotics (ASHs)

Hetlioz (Tasimelteon) capsules Clinical Criteria Logic Diagram





Anxiolytics and Sedatives/Hypnotics (ASHs)

Hetlioz LQ (Tasimelteon) suspension Clinical Criteria Logic

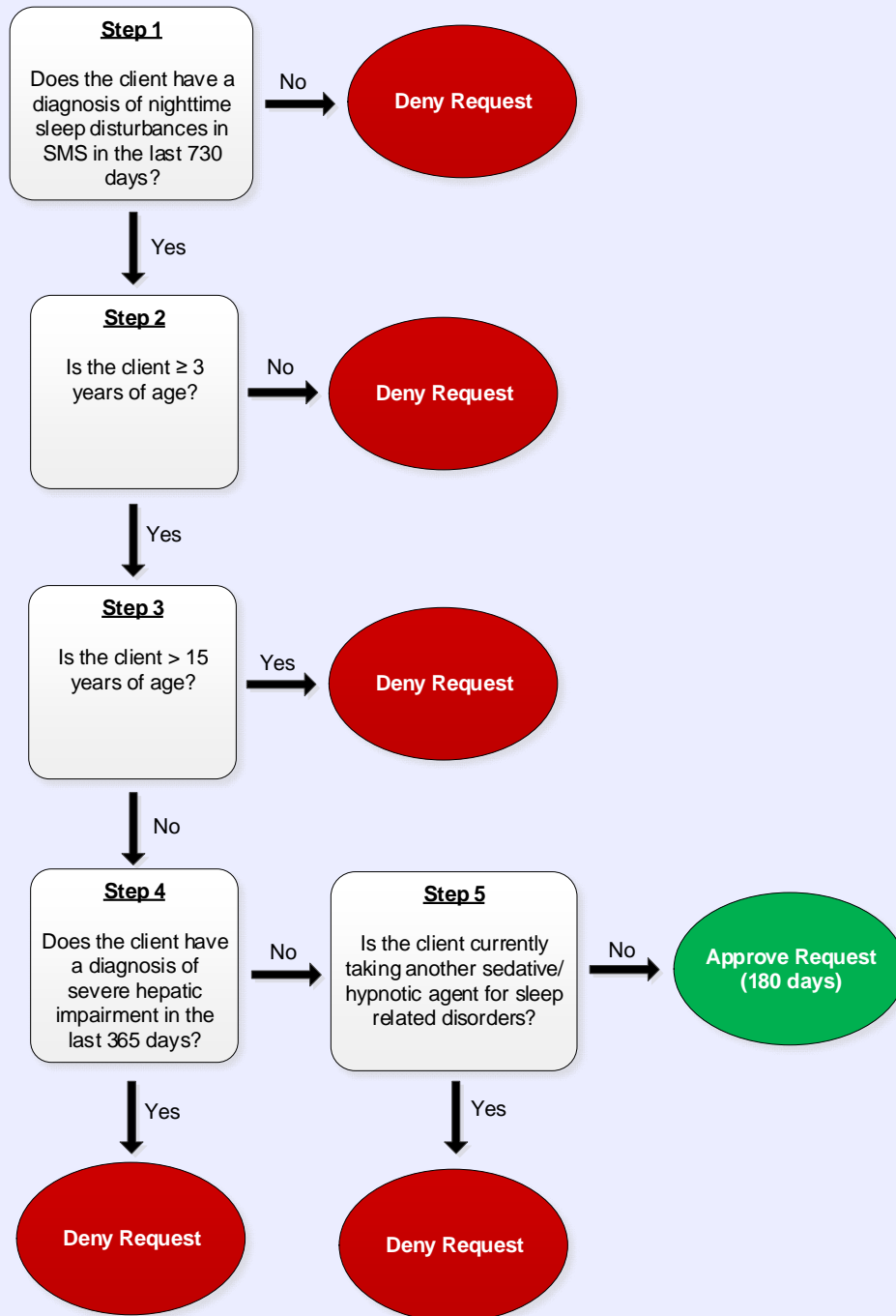
1. Does the client have a diagnosis of nighttime sleep disturbances in **Smith-Magenis Syndrome (SMS)** in the last 730 days?
 Yes (Go to #2)
 No (Deny)
2. Is the client greater than or equal to (\geq) 3 years of age?
 Yes (Go to #3)
 No (Deny)
3. Is the client greater than ($>$) 15 years of age?
 Yes (Deny)
 No (Go to #4)
4. Does the client have a diagnosis of **severe hepatic impairment** in the last 365 days?
 Yes (Deny)
 No (Go to #5)
5. Is the client currently taking another **sedative/hypnotic agent** for sleep related disorders?
 Yes (Deny)
 No (Approve – 180 days)



Anxiolytics and Sedatives/Hypnotics (ASHs)

Hetlioz LQ (Tasimelteon) suspension

Clinical Criteria Logic Diagram





Anxiolytics and Sedatives/Hypnotics (ASHs)

Hetlioz (Tasimelteon) Clinical Criteria Supporting Tables

Diagnosis of N24SWD Required diagnosis: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
G4724	CIRCADIAN RHYTHM SLEEP DISORDER, FREE RUNNING TYPE

Diagnosis of Smith Magenis Syndrome Required diagnosis: 1 Look back timeframe: 730 days	
ICD-10 Code	Description
Q9388	OTHER MICRODELETIONS

Hepatic Disease/Impairment Required diagnosis: 1 Look back timeframe: 365 days	
ICD-10 Code	Description
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA

Hepatic Disease/Impairment	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS

Hepatic Disease/Impairment	
Required diagnosis: 1	
Look back timeframe: 365 days	
ICD-10 Code	Description
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE

Sedative/Hypnotic Agents	
Label Name	GCN
AMBIEN 5 MG TABLET	00870
AMBIEN 10 MG TABLET	00871
AMBIEN CR 6.25 MG TABLET	25456
AMBIEN CR 12.5 MG TABLET	25457
BELSOMRA 10 MG TABLET	36968
BELSOMRA 15 MG TABLET	36969
BELSOMRA 20 MG TABLET	36971
BELSOMRA 5 MG TABLET	36967
BUTISOL SODIUM 30 MG TABLET	13102
DAYVIGO 10 MG TABLET	47484
DAYVIGO 5 MG TABLET	47479
EDLUAR 5 MG SL TABLET	26183
EDLUAR 10 MG SL TABLET	26182

Sedative/Hypnotic Agents	
Label Name	GCN
ESTAZOLAM 1 MG TABLET	19181
ESTAZOLAM 2 MG TABLET	19182
ESZOPICLONE 1 MG TABLET	23927
ESZOPICLONE 2 MG TABLET	23926
ESZOPICLONE 3 MG TABLET	23925
FLURAZEPAM 15 MG CAPSULE	14250
FLURAZEPAM 30 MG CAPSULE	14251
LUNESTA 1 MG TABLET	23927
LUNESTA 2 MG TABLET	23926
LUNESTA 3 MG TABLET	23925
RESTORIL 7.5 MG CAPSULE	13845
RESTORIL 15 MG CAPSULE	13840
RESTORIL 22.5 MG CAPSULE	24036
RESTORIL 30 MG CAPSULE	13841
ROZEREM 8 MG TABLET	25202
TEMAZEPAM 7.5 MG CAPSULE	13845
TEMAZEPAM 15 MG CAPSULE	13840
TEMAZEPAM 22.5 MG CAPSULE	24036
TEMAZEPAM 30 MG CAPSULE	13841
TRIAZOLAM 0.125 MG TABLET	14282
TRIAZOLAM 0.25 MG TABLET	14280
ZALEPLON 5 MG CAPSULE	92713
ZALEPLON 10 MG CAPSULE	92723
ZOLPIDEM TART 1.75 MG TABLET SL	31562
ZOLPIDEM TART 3.5 MG TABLET SL	31563
ZOLPIDEM TART ER 6.25 MG TAB	25456
ZOLPIDEM TART ER 12.5 MG TAB	25457
ZOLPIDEM TARTRATE 5 MG TABLET	00870
ZOLPIDEM TARTRATE 10 MG TABLET	00871



Anxiolytics and Sedatives/Hypnotics (ASHs)

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc. 2021. Available at <http://www.clinicalpharmacology.com>. Accessed on July 23, 2021.
2. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on July 23, 2021.
3. Hetlioz Prescribing Information. Washington, D.C. Vanda Pharmaceuticals, Inc. December 2020.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
07/23/2021	Criteria revised for presentation to the DUR Board