

Title

Hypnotics

Ambien[®] (zolpidem)
Ambien CR[™] (zolpidem, controlled release)
Lunesta[™] (eszopiclone)
Rozerem[™] (ramelteon)
Sonata[®] (zaleplon)

Prescription Drug Step Therapy

Note: Prescription drugs are covered to the extent that these types of services are generally covered by each member's pharmacy benefit design. The Formulary Exception/Prior Authorization form is included as part of this document for prescribers to submit for patients who do not meet the step therapy criteria at the point-of-sale.

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

Drug	Formulary Information			
	Standard		Blue Value Rx	
	Formulary Status	Step	Formulary Status	Step
Doral [®]	Covered	1	Not Covered*	1
Dalmane [®]	Covered	1	Not Covered*	1
estazolam	Covered	1	Covered	1
flurazepam	Covered	1	Covered	1
Halcion [®]	Covered	1	Not Covered*	1
ProSom [™]	Covered	1	Not Covered*	1
Restoril [®]	Not Covered*	1	Not Covered*	1
temazepam	Covered	1	Covered	1
triazolam	Covered	1	Covered	1
zaleplon	Covered	1	Covered	1
zolpidem	Covered	1	Covered	1
Lunesta ^{™ 2}	Covered	2	Covered	2
Ambien ^{® 2}	Covered	3	Not Covered	3
Ambien CR ^{™ 2}	Not Covered	3	Not Covered	3
Rozerem ^{™ 2}	Not Covered	3	Not Covered	3
Sonata ^{® 2}	Covered	3	Not Covered	3

* Formulary Exception required. If approved, will satisfy the step 1 requirement.

When services are covered

We cover the hypnotic medications listed in the chart above for new starts* in the following stepped approach¹:

*New start is defined as no previous paid claim for the requested medication within the past 180 days.

Step 1: Formulary step 1 medications will be covered without prior authorization.

Step 2: Formulary step 2 medications will be covered when one of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 1 drug within the previous 180 days.

OR

- There must be evidence of a BCBSMA paid claim by the patient of a Step 2 drug within the previous 180 days.

Step 3: Multi-source Brands and Non-Formulary medications* when one of the following criteria is met:

*Non-formulary medications also require a formulary exception request to be submitted and approved by BCBSMA Pharmacy Operations in addition to meeting the criteria below

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 1 drug within the previous 180 days.

AND

- There must be evidence of a BCBSMA paid claim or physician documented use, excluding the use of samples, by the patient of a Step 2 drug within the previous 180 days.

OR

- There must be evidence of a BCBSMA paid claim by the patient of a Step 3 drug within the previous 180 days.

When services are not covered

We do not cover drugs listed in the above chart when the above step therapy criteria are not met.

Individual consideration

All our policies are written for the majority of people with given conditions. For many of our policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Prescribers may send relevant clinical information for individual patients for coverage consideration to:

Blue Cross Blue Shield of Massachusetts
Clinical Pharmacy Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Managed care, PPO and Indemnity guidelines

- Step Therapy is required when these drugs are processed through our point of sale electronic pharmacy benefit.
- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria for hypnotic medications at the point of sale.
Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step-therapy criteria for hypnotic medications at the point of sale.

Coding information

- Physician billing is not applicable as these medications are billed through the pharmacy benefit

Definitions

Hypnotics: a class of drugs that induce sleep.

Insomnia: inability to sleep or to remain asleep throughout the night.

Multi-source brand: medications that have more than one brand name drug that has a similar clinical formula where the drugs are considered therapeutically interchangeable Multi-source drugs will also have generics available after a patent expires.

Policy update history

Reviewed 2/07 MPG Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made.

Updated 6/07 to add zolpidem to Step 1 and move Ambien® to Step 2. Updated 12/07 to move Ambien® to Step 3 as a multi-source brand. Updated 6/08 to include new generic zaleplon and movement of Sonata® to Step 3 as a multi-source brand.

Scientific background, Rationale and References

¹ Based on the recommendations of the BCBSMA Pharmacy and Therapeutics committee meeting on 2/15/06.

² Quality Care Dosing Guidelines apply. Please see Pharmacy Medical Policy #621

References

- Silber, MH. Chronic Insomnia. *The New England Journal of Medicine* 2005;35(8):803-810.
- National Institutes of Health State of the Science Conference Statement. Manifestations and management of chronic insomnia in adults. June 13-15, 2005. Draft statement on June 15, 2005. Accessed on 03/23/2006. Available at: <http://consensus.nih.gov/ta/026/InsomniaDraftStatement061505.pdf>
- Buscemi N, Vandermeer B, Friesen C, Bialy L, Tubman M, Ospina, M, Klassen TP, Witmans M. Manifestations and Management of Chronic Insomnia in Adults. Summary, Evidence Report/Technology Assessment No. 125 (Prepared by the University of Alberta Evidence-based Practice Center, under contract No. C400000021.) AHRQ Publication No. 05-E021-1. Rockville, MD: Agency for Healthcare Research and Quality. June 2005
- Ambien® [package insert]. New York, NY: Sanofi-Synthelabo, Inc.; March 2004.
- Sonata® [package insert]. Bristol, TN: King Pharmaceuticals; July 2003.
- Lunesta™ [package insert]. Marlborough, MA: Sepracor, Inc.; February 2005.
- Ambien CR™ [package insert]. New York, NY: Sanofi-Synthelabo, Inc.; August 2005.
- Rozerem™ [package insert]. Lincolnshire, IL: Takeda Pharmaceuticals, Inc; August 2005. FL, May 21-23, 2005.

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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Request for Outpatient Retail Pharmacy Prior Authorization for Hypnotics (#033)

Fax to: Clinical Pharmacy Program (800) 583-6289 or for
Medicare Advantage HMO Blue /PPO Blue: (866)463-7700

We plan to respond to your request within two business days of our receipt. To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number. We cannot process requests unless they contain all of the information requested below:

Patient Information (REQUIRED)	
Name	
BCBSMA ID Number	
Is the patient a BCBSMA employee? If yes, please fax request to: (617) 246-4013	Yes No
Date of Birth	__ __ / __ __ / __ __ __ __
Patient's Diagnosis or ICD-9-CM code	
Physician Information (REQUIRED)	
Name	
Medical Specialty	
BCBSMA Provider number	
Telephone Number	
Fax Number	
Contact Name (if different from physician)	
Outpatient Retail Pharmacy Prior Authorization Request	
Step 1 medications:	Doral® Dalmane® estazolam flurazepam Halcion® ProSom™ Restoril® temazepam triazolam zaleplon zolpidem
Step 2 medications:	Lunesta™
Step 3 medications:	Ambien® Ambien CR™ Rozerem™ Sonata®
Dose: _____ Sig: _____ Qty: _____	*Please see lower box for QCD overrides
Clinical Information for Step 2 & Step 3 medications :	
Previous treatment failure (excluding samples) within the previous 180 days (please check all that apply):	
Ambien®	flurazepam Rozerem™ zolpidem
Ambien CR™	Halcion® Sonata®
Dalmane®	Lunesta™ temazepam
Doral®	ProSom™ triazolam
estazolam	Restoril® zaleplon
other clinical reason (please specify): _____	
Quality Care Dosing Override Request: Quantity Requested: _____ Clinical reason for override of QCD limit: _____	
MD Signature:	Date: