Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization

Title: Progressive Medication Program for Insomnia Agents (Lunesta®, Rozerem®, and Zolpidem Tartrate ER)

Approval: Robert Bonnell, M.D., Med. Dir.

DATES - Origination: 08/30/12

Responsible Party: CPM Director

Revised: 08/30/12

Effective: 08/30/12

Distribution: Medical Department

P&T Review: 11/18/15

Annual Review: 11/18/15

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Implementation Information:

1.0 Under the supervision of the Clinical Pharmacy Management (CPM) Director, the CPM staff is responsible for the development of guidelines and criteria for use by the Medical Department.

2.0 Staff utilizing this procedure is monitored via individual departmental audit tools.

3.0 On an annual basis or more often when indicated, the Medical Department Procedures are reviewed by medical staff for the purpose of developing, revising, or archiving:

3.1 Medical Department staff has access to the Medical Department Procedure Manual and receives notice from management when procedures are developed, updated and/or revised, or archived.

Background Information:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Additional Information

- AvMed’s Clinical Pharmacists are licensed by the State of Florida.
- AvMed’s Medical Directors are Board Certified physicians licensed by the State of Florida.
Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization

Number: 07.118

Page 2 of 3

Title: Progressive Medication Program for Insomnia Agents
     (Lunesta®, Rozerem®, and Zolpidem Tartrate ER)

Background Information, continued:

Medication Summary

- Zolpidem tartrate and eszopiclone (Lunesta®) are non-benzodiazepine sedative hypnotics for the treatment of insomnia. Zolpidem tartrate ER is indicated for insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Lunesta® is indicated for the treatment of insomnia. Ramelteon (Rozerem®) is indicated for the treatment of chronic or transient insomnia characterized by difficulty with sleep onset.
- Both zolpidem and eszopiclone (Lunesta®) act on the GABA<sub>A</sub> receptor complex on the alpha-subunit (the benzodiazepine (BZ) or omega receptor). Zolpidem preferentially binds to the omega-1 receptor, possibly explaining its lack of anxiolytic, muscle relaxant and anticonvulsant effects. Eszopiclone non-selectively binds to all three (3) GABA<sub>A</sub> receptor subtypes.
- Ramelteon (Rozerem®) is a selective melatonin receptor agonist. It targets receptors MT1 and MT2 (3-16 times higher affinity than melatonin) in the suprachiasmatic nucleus (SCN) of the hypothalamus. The SCN functions as the body’s internal clock and regulates the 24-hour sleep-wake cycle. The MT1 and MT2 receptors are involved in the promotion of sleep and the maintenance of normal circadian rhythm when acted upon by endogenous melatonin.
- All sedative hypnotics should be taken immediately before retiring. Taking a sedative hypnotic while still up and about may induce short-term memory impairment, hallucinations, impaired coordination, dizziness, and lightheadedness.

Coverage Guidelines

- Member must be eligible for benefit coverage within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusion Criterion

- Members less than 18 years of age.
Medical Department Procedure Manual

Section: Chapter 7A Prescription Medication Prior Authorization            Number: 07.118
Title: Progressive Medication Program for Insomnia Agents (Lunesta®, Rozerem®, and Zolpidem Tartrate ER)

Procedure:

1.0 Request for initial therapy with Lunesta®, Rozerem®, and Zolpidem Tartrate ER for insomnia requires documentation from the Member’s medical records maintained by the requesting independent practitioner’s office verifying the following:

1.1 Member is new Member to AvMed (eligibility within the past 120 days) and has been on targeted medication prior to joining AvMed (evidenced by progress notes from prescriber indicating use or documented previous fill history with pharmacy);

OR

1.1 Member has tried and failed an adequate trial (at least 2 consecutive months) of at least one (1) of the following medications, immediate release zolpidem or zaleplon;

1.2 If criterion is met, request may be approved for one (1) month with a quantity limit of 30 tablets for 30 days:

1.2.1 Refills should continue to process every month thereafter.

References:


2. Lunesta Prescribing Information, Sunovion Pharmaceuticals, Marlborough, MA November 2010.

3. Rozerem Prescribing Information, Takeda Pharmaceuticals America, Inc. Deerfield, IL 60015, November 2010.