

Criteria for Indiana Medicaid Sedative Hypnotics/Benzodiazepine PA with QL

Prepared for State of Indiana by OptumRx

EXECUTIVE SUMMARY

Purpose: Promote prudent prescribing of Sedative-Hypnotics and Benzodiazepines

Setting & Population: All members

Type of Criteria: Increased Risk of ADE Non-Preferred Agent
 Appropriate Indications Other:

Data Sources: Only administrative databases Databases + Prescriber-supplied databases

| TARGETED PRODUCTS | |
|--|--------------------------|
| BENZODIAZEPINES | |
| ATIVAN (LORAZEPAM) | ONFI (CLOBAZAM) |
| DALMANE (FLURAZEPAM) | PROSOM (ESTAZOLAM) |
| DORAL (QUAZEPAM) | RESTORIL (TEMAZEPAM) |
| HALCION (TRIAZOLAM) | SERAX (OXAZEPAM) |
| KLONOPIN (CLONAZEPAM) | TRANXENE T (CLORAZEPATE) |
| LIBRAX (CHLORDIAZEPOXIDE-CLIDINIUM) | VALIUM (DIAZEPAM) |
| LIBRIUM (CHLORDIAZEPOXIDE) | VERSED SYRUP (MIDAZOLAM) |
| LIMBITROL (CHLORDIAZEPOXIDE-AMITRIPTYLINE) | XANAX (ALPRAZOLAM) |
| LOREEV XR (LORAZEPAM) | XANAX XR (ALPRAZOLAM) |
| DUAL OREXIN RECEPTOR ANTAGONISTS (DORA) | |
| BELSOMRA (SUVOREXANT) | DAYVIGO (LEMBOREXANT) |
| QUVIVIQ (DARIDOREXANT) | |
| SEDATIVE HYPNOTICS | |
| AMBIEN (ZOLPIDEM) | INTERMEZZO (ZOLPIDEM) |
| AMBIEN CR (ZOLPIDEM) | LUNESTA (ESZOPICLONE) |
| AMYTAL (AMOBARBITAL SODIUM) | SONATA (ZALEPLON) |
| EDLUAR (ZOLPIDEM) | ZOLPIMIST (ZOLPIDEM) |
| EQUANIL (MEPROBAMATE) | ZOLPIDEM CAPSULE |

APPROVAL DURATION

- Approvals will be granted for up to 1 year unless otherwise specified in criteria below

APPROVAL CRITERIA

Prior authorization for the prescribed drug will be granted when the following approval criteria has been met:

INITIATION OF SHORT-TERM BENZODIAZEPINE THERAPY*

*Members may utilize benzodiazepines without requiring prior authorization within the **plan limitation maximum** of 15-day supply with a subsequent claim(s) not to exceed 15-day supply (for a total of 30 days of therapy) every 90 days. To exceed this plan limitation, member must meet **Initiation of Long-Term Benzodiazepine Therapy** criteria.

Initiation of benzodiazepine therapy (lack of claims history of 90 days of therapy within the past 180 days) for short-term use must meet the utilization edits listed in Table 1 (Utilization Edits for Initial Benzodiazepine Utilizers and Concurrent Benzodiazepine/Opioid Therapy)

Note: Concurrent use with opioid therapy must meet **Benzodiazepine and Opioid Concurrent Therapy** criteria (see below, maximum of 7 days of concurrent therapy every 180 days). Utilization of benzodiazepines with carisoprodol and combinations will require prior authorization for medical necessity. Criteria does not apply to chlordiazepoxide-clidinium and clobazam.

INITIATION OF LONG-TERM BENZODIAZEPINE THERAPY*

*Request to exceed the plan limitation maximum of 15-day supply with a subsequent claim(s) not to exceed 15-day supply (for a total of 30 days of therapy) every 90 days.

Initiation of benzodiazepine therapy (lack of claims history of 90 days of therapy within the past 180 days) for long-term use must meet the utilization edits listed in Table 1 (Utilization Edits for Initial Benzodiazepine Utilizers and Concurrent Benzodiazepine/Opioid Therapy).

Note: Concurrent use with opioid therapy must meet **Benzodiazepine and Opioid Concurrent Therapy** criteria (see below, maximum of 7 days of concurrent therapy every 180 days). Utilization of benzodiazepines with carisoprodol and combinations will require prior authorization for medical necessity. Criteria does not apply to chlordiazepoxide-clidinium and clobazam.

Must meet one of the following:

- Diagnosis of cancer, seizure disorder, catatonia (may exceed plan limitations; approval duration 6 months), intractable Meniere's disease, or other terminal illness
- Diagnosis of spasticity associated with a central neurological disorder (e.g., cerebral palsy, dystonia, paraplegia, etc.) and both of the following:
 - Requested agent has compendia indication for spasticity
 - One of the following:
 - Prescribed by, or in consultation with, a neurologist or physical medicine and rehabilitation specialist
 - Previous trial and failure of at least two non-benzodiazepine muscle relaxants
- Diagnosis of akathisia and one of the following:
 - Previous trial and failure of propranolol
 - Prescriber has provided medical rationale for the use of a benzodiazepine over propranolol
- Provider has submitted valid medical justification to exceed plan limitation maximum for initiation of benzodiazepine therapy (15-day supply with a subsequent claim(s) not to exceed 15-day supply (for a total of 30 days of therapy) every 90 days)

INITIATION OF LOREEV XR (LORAZEPAM) THERAPY

Must meet all of the following:

- Member has current approval for long-term benzodiazepine therapy (1 year or greater) or qualifies for long-term approval of benzodiazepine therapy
- Has a history of paid claims for lorazepam IR formulation for at least 90 of the past 180 days
- History of a claim for lorazepam IR formulation at a consistent scheduled three times daily dose within the previous 30 days

Note: Concurrent use with opioid therapy must meet **Benzodiazepine and Opioid Concurrent Therapy** criteria (see below, maximum of 7 days of concurrent therapy every 180 days). Utilization of benzodiazepines with carisoprodol and combinations will require prior authorization for medical necessity.

CONTINUATION OF LONG-TERM BENZODIAZEPINE THERAPY*

*Continuation of benzodiazepine therapy must meet the utilization edits listed in Table 2 (Utilization Edits for Current Benzodiazepine Utilizers)

Note: Concurrent use with opioid therapy must meet **Benzodiazepine and Opioid Concurrent Therapy** criteria (see below, maximum of 7 days of concurrent therapy every 180 days). Utilization of benzodiazepines with carisoprodol and combinations will require prior authorization for medical necessity.

Must meet the following:

- History of the requested agent for 90 of the past 180 days (confirmed by claims history)

DUPLICATE SEDATIVE HYPNOTICS/BENZODIAZEPINE/DORA THERAPY

- Must meet all of the following:
 - One of the following:
 - Agents involved in the therapeutic duplication are being cross tapered (45-day approval only)
 - Agent in history is being discontinued or there are plans to discontinue it (45-day approval only)
 - Medical rationale supporting duplication of therapy (to be reviewed by the clinical call center for medical necessity)
 - Must meet established utilization edits (Tables 1, 2, 3, and 4)*

*Members initiating of benzodiazepine therapy (lack of claims history of 90 days of therapy within the past 180 days) must meet utilization edits in Table 1; Members continuing long-term benzodiazepine therapy (claims history of the requested agent for 90 of the past 180 days) must meet utilization edits in Table 2

Note: Prior authorization is not required for duplication of rectal or nasal benzodiazepine preparations in combination with oral therapy. Prior authorization is not required for short duration of duplicate benzodiazepine/sedative hypnotic for acute/procedural needs. Clobazam claim with seizure diagnosis is exempt.

BENZODIAZEPINE AND OPIOID CONCURRENT THERAPY*

*Requests for benzodiazepine therapy exceeding a 7-day supply every 180 days OR benzodiazepine therapy exceeding utilization edits listed in Table 1

- Must meet all of the following:
 - Indications provided for both the benzodiazepine agent(s) and the opioid agent(s)
 - Documentation of previous therapies attempted for the indication(s) above
 - **Prescriber signed attestation:**
 - The member's INSPECT report has been evaluated and continues to be evaluated on a regular basis

- The member has been educated in regard to the risks of concurrent utilization of benzodiazepine therapy, and the member accepts these risks
- The prescriber has consulted any other prescribers involved in concurrent therapy and all prescribers agree to pursue concurrent opioid and benzodiazepine therapy for the member, if applicable
- The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma, and death, associated with concurrent utilization
- Must meet utilization edits (see Table 1 – Utilization Edits for Initial Benzodiazepine Utilizers and Concurrent Benzodiazepine/Opioid Therapy)

Notes:

- Concurrent utilization will include members with a claim for an opiate in the past 30 days
- Current utilizers of benzodiazepines and opiates concurrently (utilizing concomitant therapy for 90 of the past 120 days, confirmed by claims history) will be exempt from this PA criteria at this time
- Clobazam claim with seizure diagnosis is exempt.
- Utilization of benzodiazepines with carisoprodol and combinations will require prior authorization for medical necessity
- Documentation will be reviewed for medical necessity including, but not limited to, appropriate diagnoses and trials of other agents
- **Prescriber must submit documentation via fax form with signed attestation**

Table 1 – Utilization Edits for Initial Benzodiazepine Utilizers and Concurrent Benzodiazepine/Opioid Therapy

| Drug | Dose | QL |
|--------------------------------|-----------|----------|
| alprazolam | 0.25 mg | 3/day |
| alprazolam | 0.5 mg | 3/day |
| alprazolam | 1 mg | PA Req'd |
| alprazolam | 2 mg | PA Req'd |
| alprazolam concentrate | 1 mg/mL | PA Req'd |
| alprazolam ODT | 0.25 mg | 3/day |
| alprazolam ODT | 0.5 mg | 3/day |
| alprazolam ODT | 1 mg | PA Req'd |
| alprazolam ODT | 2 mg | PA Req'd |
| alprazolam ER | 0.5 mg | PA Req'd |
| alprazolam ER | 1 mg | PA Req'd |
| alprazolam ER | 2 mg | PA Req'd |
| alprazolam ER | 3 mg | PA Req'd |
| chlordiazepoxide | 5 mg | 3/day |
| chlordiazepoxide | 10 mg | 3/day |
| chlordiazepoxide | 25 mg | PA Req'd |
| chlordiazepoxide-amitriptyline | 5-12.5 mg | PA Req'd |
| chlordiazepoxide-amitriptyline | 10-25 mg | PA Req'd |
| clonazepam | 0.5 mg | 2/day |
| clonazepam | 1 mg | PA Req'd |
| clonazepam | 2 mg | PA Req'd |
| clonazepam ODT | 0.125 mg | 2/day |

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|------------------------|------------|------------------------------|
| clonazepam ODT | 0.25 mg | 2/day |
| clonazepam ODT | 0.5 mg | 2/day |
| clonazepam ODT | 1 mg | PA Req'd |
| clonazepam ODT | 2 mg | PA Req'd |
| clorazepate | 3.75 mg | 2/day |
| clorazepate | 7.5 mg | 2/day |
| clorazepate | 15 mg | 2/day |
| diazepam | 2 mg | 2/day |
| diazepam | 5 mg | 2/day |
| diazepam | 10 mg | PA Req'd |
| diazepam concentrate | 5 mg/mL | PA Req'd |
| diazepam oral solution | 1 mg/mL | 10 mL/day |
| estazolam | 1 mg | 1/day |
| estazolam | 2 mg | PA Req'd |
| flurazepam | 15 mg | 1/day |
| flurazepam | 30 mg | PA Req'd |
| lorazepam | 0.5 mg | 3/day |
| lorazepam | 1 mg | 3/day |
| lorazepam | 2 mg | PA Req'd |
| lorazepam concentrate | 1 mg/0.5mL | PA Req'd |
| lorazepam concentrate | 2 mg/mL | PA Req'd |
| lorazepam ER | 1 mg | PA Req'd; 18 years and older |
| lorazepam ER | 1.5 mg | PA Req'd; 18 years and older |
| lorazepam ER | 2 mg | PA Req'd; 18 years and older |
| lorazepam ER | 3 mg | PA Req'd; 18 years and older |
| Midazolam | | PA Req'd |
| oxazepam | 10 mg | 3/day |
| oxazepam | 15 mg | 3/day |
| oxazepam | 30 mg | PA Req'd |
| quazepam | 15 mg | 1/day |
| temazepam | 7.5 mg | 1/day |
| temazepam | 15 mg | 1/day |
| temazepam | 22.5 mg | PA Req'd |
| temazepam | 30 mg | PA Req'd |
| triazolam | 0.125 mg | 2 tabs/10 days |
| triazolam | 0.25 mg | 2 tabs/10 days |

Table 2 – Utilization Edits for Current Benzodiazepine Utilizers

| Drug | Dose | QL |
|------------|---------|-------|
| alprazolam | 0.25 mg | 4/day |
| alprazolam | 0.5 mg | 4/day |

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|--------------------------------|------------|---------------------------|
| alprazolam | 1 mg | 4/day |
| alprazolam | 2 mg | 4/day |
| alprazolam concentrate | 1 mg/mL | 4mL/day |
| alprazolam ODT | 0.25 mg | 4/day |
| alprazolam ODT | 0.5 mg | 4/day |
| alprazolam ODT | 1 mg | 4/day |
| alprazolam ODT | 2 mg | 4/day |
| alprazolam ER | 0.5 mg | 1/day |
| alprazolam ER | 1 mg | 1/day |
| alprazolam ER | 2 mg | 1/day |
| alprazolam ER | 3 mg | 1/day |
| chlordiazepoxide | 5 mg | 4/day |
| chlordiazepoxide | 10 mg | 4/day |
| chlordiazepoxide | 25 mg | 4/day |
| chlordiazepoxide-amitriptyline | 5-12.5 mg | |
| chlordiazepoxide-amitriptyline | 10-25 mg | |
| clonazepam | 0.5 mg | 3/day |
| clonazepam | 1 mg | 3/day |
| clonazepam | 2 mg | 3/day |
| clonazepam ODT | 0.125 mg | 3/day |
| clonazepam ODT | 0.25 mg | 3/day |
| clonazepam ODT | 0.5 mg | 3/day |
| clonazepam ODT | 1 mg | 3/day |
| clonazepam ODT | 2 mg | 3/day |
| clorazepate | 3.75 mg | 4/day |
| clorazepate | 7.5 mg | 4/day |
| clorazepate | 15 mg | 4/day |
| diazepam | 2 mg | 4/day |
| diazepam | 5 mg | 4/day |
| diazepam | 10 mg | 4/day |
| diazepam concentrate | 5 mg/mL | 8 mL/day |
| diazepam oral solution | 1 mg/mL | |
| estazolam | 1 mg | 1/day |
| estazolam | 2 mg | 1/day |
| flurazepam | 15 mg | 1/day |
| flurazepam | 30 mg | 1/day |
| lorazepam | 0.5 mg | 4/day-max qty 120 |
| lorazepam | 1 mg | 4/day-max qty 120 |
| lorazepam | 2 mg | 4/day-max qty 120 |
| lorazepam concentrate | 1 mg/0.5mL | |
| lorazepam concentrate | 2 mg/mL | |
| lorazepam ER | 1 mg | 1/day; 18 years and older |

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|-------------------------------|----------|---------------------------|
| lorazepam ER | 1.5 mg | 1/day; 18 years and older |
| lorazepam ER | 2 mg | 2/day; 18 years and older |
| lorazepam ER | 3 mg | 3/day; 18 years and older |
| midazolam syrup and injection | | |
| oxazepam | 10 mg | 4/day-max qty 120 |
| oxazepam | 15 mg | 4/day-max qty 120 |
| oxazepam | 30 mg | 4/day-max qty 120 |
| quazepam | 15 mg | 1/day |
| temazepam | 7.5 mg | 1/day |
| temazepam | 15 mg | 1/day |
| temazepam | 22.5 mg | 1/day |
| temazepam | 30 mg | 1/day |
| triazolam | 0.125 mg | 1/day |
| triazolam | 0.25 mg | 1/day |

Table 3 – Utilization Edits for Sedative Hypnotics

| Drug | Dose | QL |
|--------------------|-------------|------------------|
| amobarbital sodium | 500 mg/mL | |
| eszopiclone | 1 mg | 1/day |
| eszopiclone | 2 mg | 1/day |
| eszopiclone | 3 mg | 1/day |
| meprobamate | 200 mg | 4/day |
| meprobamate | 400 mg | 4/day |
| zaleplon | 5 mg | 2/day |
| zaleplon | 10 mg | 2/day |
| zolpidem capsule | 7.5 mg | 1/day |
| zolpidem | 5 mg | 1/day |
| zolpidem | 10 mg | 1/day |
| zolpidem CR | 6.25 mg | 1/day |
| zolpidem CR | 12.5 mg | 1/day |
| zolpidem SL | 1.75 mg | 1/day |
| zolpidem SL | 3.5 mg | 1/day |
| zolpidem SL | 5 mg | 1/day |
| zolpidem SL | 10 mg | 1/day |
| zolpidem solution | 5 mg/act | 2 actuations/day |

Table 4 – Utilization Edits for Dual Orexin Receptor Antagonists

| Drug | Dose | QL |
|--------------|-------------|-------------------------------|
| daridorexant | 25 mg | 1/day; Age years 18 and older |
| daridorexant | 50 mg | 1/day; Age years 18 and older |
| lemborexant | 5 mg | 1/day; Age years 18 and older |
| lemborexant | 10 mg | 1/day; Age years 18 and older |
| suvorexant | 5 mg | 1/day; Age years 18 and older |
| suvorexant | 10 mg | 1/day; Age years 18 and older |
| suvorexant | 15 mg | 1/day; Age years 18 and older |
| suvorexant | 20 mg | 1/day; Age years 18 and older |

- Existing Criteria
- Revision of Existing Criteria
- New Criteria