Clinical Policy: Benzodiazepine/ Sedative Hypnotics

Reference Number: IN.CP.PPA.13
Effective Date: 10.2018
Last Review Date: 06.2022
Line of Business: Medicaid

Revision Log

Description

Promote prudent prescribing of Sedative-Hypnotics and Benzodiazepines and Dual orexin receptor antagonist (DORA) agents. To limit the unsafe concurrent use of benzodiazepine and opioids or carisoprodol containing products through medical necessity review.

FDA Approved Indication(s)

All edits are based on FDA labeling as published by the manufacturer

Brand

Multiple Medication classes are included in this edit

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

NOTES:

- Concurrent utilization will include members with a claim for an opiate in the past 30 days
- Prescriber must submit documentation via fax form with signed attestation for concurrent use of a benzodiazepine and opiate.
- Current utilizers of benzodiazepines (utilizing for 90 of the past 180 days) will be exempt from this PA criteria
- 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

It is the policy of MHS that concurrent use of benzodiazepines with opioids or carisoprodol when the following criteria are met:

I. Benzodiazepine and Opioids Concurrent Therapy (for benzodiazepine therapy exceeding 7 days in 180 days OR benzodiazepine therapy exceeding quantity limits for initiation of concurrent therapy):

A. Must provide diagnoses for both agents. Excluded diagnosis: Cancer, seizure disorder, catatonia and other terminal illness.

i. AND

B. Must provide previous therapy attempted

i. AND

C. Prescriber must sign attestation confirming

1. The member's INSPECT report has been evaluated and regular review will occur.
2. That the prescriber has educated the member of the risks of concurrent utilization,
3. The prescriber and member accept the risks associated with concurrent utilization
4. The prescriber acknowledges the risk of adverse event(s), including respiratory depression, coma and death associated with concurrent utilization.

https://www.mhsindiana.com/content/dam/centene/mhsindiana/medicaid/pdfs/508-Opioid-BZD-Concurrency-PA.pdf

i. AND

D. Must meet utilization edits (see Appendix A below)

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 for 90 of the past 180 days) will be exempt from this PA criteria
- 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

Approval duration: Up to 12 months

II. Criteria for concurrent carisoprodol and benzodiazepine

A. Documentation shows medical necessity for carisoprodol over preferred muscle agents.

B. Review member recent 6 month claim history for trial of other muscle relaxants

C. Prescriber must submit document via fax form and signed attestation.

III. Criteria for initiation of benzodiazepine therapy

A. . Must meet one of the following

1. Seizure disorder
2. Cancer diagnosis
3. Terminal illness
4. Intractable Meniere'
5. Catatonia (may exceed plan limitations) Approval: 6 months

6. Diagnosis of spasticity associated with central neurological disorder (i.e.: cerebral palsy, dystonia, paraplegia)
    a. One of the following
        i. Requested agents has compendia indication for spasticity
        ii. One of the following
            1. Prescribed by or in consultation with a neurologist or physical medicine and rehabilitation specialist
            2. Previous trial and failure of at least two non-benzodiazepine muscle relaxants.
7. Akathisia Must meet one of the following:
    a. Previous trial and failure of propranolol
    b. 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

Approve for 6 months.

B. If member does not have one of the above diagnoses,

1. Did they fill benzodiazepine 90 of the last 180 days, if so approve for 12 months?
2. If they filled a benzodiazepine less than 90 days of the last 180 days, deny.
3. If not on a benzodiazepine previously member can have two 15 day fills with no PA. (total of 30 days of benzodiazepine coverage out of 90 days with no PA)
4. Will allow a cross taper for 45 days if member is changing from one benzodiazepine to another.
5. Dose must meet utilization edits (see Appendix B below)
6. Approve for 12 months

IV. Initiation of Loreev XR (Lorazepam) therapy Must meet both of the following.

A. History of lorazepam IR formulation for at least 90 of the past 180 days
B. History of claim for lorazepam IR formulation at a consistent scheduled TID dose within previous 30 days
C. Approve for 12 months

V Duplicate Sedative Hypnotics / Benzodiazepine/DORA therapy (Must meet all A & B)

A. One of the following
    1. Agents involved in the therapeutic duplication are being cross tapered (45-day approval only.
    2. Agent in the history is being discontinued or there are plans to discontinue it (45-day approval only)
    3. Medical rationale supporting duplication of therapy (to be reviewed by the pharmacist for medical necessity)

B. Must meet established utilization edits (Appendix A, B. C and D)

Note: Members initiating benzodiazepine therapy (lack of history of 90 days of therapy within the past 180 days) must meet utilization edits in Appendix A.. Member continuing long term benzodiazepine therapy (history of the requested agent for 90 of the past 180 days) must meet utilization edits in Appendix B.

APPENDIX A Benzodiazepine with Concurrent Opioid Analgesic

Drug	Dose	QL
alprazolam	0.25mg	3/day
alprazolam	0.5mg	3/day
alprazolam	1mg	PA Req'd
alprazolam	2mg	PA Req'd
alprazolam concentrate	1mg/ml	PA Req'd
alprazolam ODT	0.25mg	3/day
alprazolam ODT	0.5mg	3/day
alprazolam ODT	1mg	PA Req'd
alprazolam ODT	2mg	PA Req'd
alprazolam ER	0.5mg	PA Req'd
alprazolam ER	1mg	PA Req'd
alprazolam ER	2mg	PA Req'd
alprazolam ER	3mg	PA Req'd
chlordiazepoxide	5mg	3/day
chlordiazepoxide	10mg	3/day
chlordiazepoxide	25mg	PA Req'd
chlordiazepoxide-amitriptyline	5-12.5mg	PA Req'd
chlordiazepoxide-amitriptyline	10-25mg	PA Req'd
clonazepam	0.5mg	2/day
clonazepam	1mg	PA Req'd
clonazepam	2mg	PA Req'd
clonazepam ODT	0.125mg	2/day
clonazepam ODT	0.25mg	2/day
clonazepam ODT	0.5mg	2/day
clonazepam ODT	1mg	PA Req'd
clonazepam ODT	2mg	PA Req'd
clorazepate	3.75mg	2/day
clorazepate	7.5mg	2/day
clorazepate	15mg	2/day
diazepam	2mg	2/day

diazepam	5mg	2/day
diazepam	10mg	PA Req'd
diazepam concentrate	5mg/ml	PA Req'd
diazepam oral solution	1mg/ml	10ml/day
estazolam	1mg	1/day
estazolam	2mg	PA Req'd
flurazepam	15mg	1/day
flurazepam	30mg	PA Req'd
lorazepam	0.5mg	3/day
lorazepam	1mg	3/day
lorazepam	2mg	PA Req'd
Lorazepam ER		PA Req'd
lorazepam concentrate	2mg/ml	PA Req'd
midazolam syrup	2mg/ml	PA Req'd
oxazepam	10mg	3/day
oxazepam	15mg	3/day
oxazepam	30mg	PA Req'd
quazepam	15mg	1/day
temazepam	7.5mg	1/day
temazepam	15mg	1/day
temazepam	22.5mg	PA Req'd
temazepam	30mg	PA Req'd
triazolam	0.125mg	2 tabs/10 days
triazolam	0.25mg	2 tabs/10 days

APPENDIX B – Utilization Edits for current benzodiazepine utilizers

Product name	Strength		Utilization Edit
XANAX	0.25	MG	4/DAY
ALPRAZOLAM	0.25	MG	4/DAY
XANAX	0.5	MG	4/DAY
ALPRAZOLAM	0.5	MG	4/DAY
XANAX	1	MG	4/DAY
ALPRAZOLAM	1	MG	4/DAY
XANAX	2	MG	4/DAY

Product name	Strength		Utilization Edit
ALPRAZOLAM	2	MG	4/DAY
ALPRAZOLAM INTENSOL	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
XANAX XR	0.5	MG	1/DAY
ALPRAZOLAM ER	0.5	MG	1/DAY
ALPRAZOLAM XR	0.5	MG	1/DAY
XANAX XR	1	MG	1/DAY
ALPRAZOLAM ER	1	MG	1/DAY
ALPRAZOLAM XR	1	MG	1/DAY
XANAX XR	2	MG	1/DAY
ALPRAZOLAM ER	2	MG	1/DAY
ALPRAZOLAM XR	2	MG	1/DAY
XANAX XR	3	MG	1/DAY
ALPRAZOLAM ER	3	MG	1/DAY
ALPRAZOLAM XR	3	MG	1/DAY
ALPRAZOLAM			
CHLORDIAZEPOXIDE HCL	5	MG	4/DAY
CHLORDIAZEPOXIDE HCL	10	MG	4/DAY
CHLORDIAZEPOXIDE HCL	25	MG	4/DAY
CLORAZEPATE DIPOTASSIUM	3.75	MG	4/DAY
TRANXENE T	7.5	MG	4/DAY
CLORAZEPATE DIPOTASSIUM	7.5	MG	4/DAY
CLORAZEPATE DIPOTASSIUM	15	MG	4/DAY
DIAZEPAM	10	MG/2ML	
VALIUM	2	MG	4/DAY
DIAZEPAM	2	MG	4/DAY
VALIUM	5	MG	4/DAY
DIAZEPAM	5	MG	4/DAY
VALIUM	10	MG	4/DAY
DIAZEPAM	10	MG	4/DAY
DIAZEPAM INTENSOL	5	MG/ML	8ML/DAY
DIAZEPAM	1	MG/ML	
DIAZEPAM	5	MG/5ML	

Product name	Strength		Utilization Edit
DIAZEPAM	5	MG/ML	
DIAZEPAM			
ATIVAN	0.5	MG	4/DAY-MAX QTY 120
LORAZEPAM	0.5	MG	4/DAY-MAX QTY 120
ATIVAN	1	MG	4/DAY-MAX QTY 120
LORAZEPAM	1	MG	4/DAY-MAX QTY 120
ATIVAN	2	MG	4/DAY-MAX QTY 120
LORAZEPAM	2	MG	4/DAY-MAX QTY 120
LORAZEPAM INTENSOL	2	MG/ML	
LORAZEPAM	2	MG/ML	
ATIVAN	2	MG/ML	
LORAZEPAM	2		
LORAZEPAM	20	MG/10 ML	
ATIVAN	4	MG/ML	
LORAZEPAM	4	MG/ML	
LORAZEPAM			
OXAZEPAM	10	MG	4/DAY-MAX QTY 120
OXAZEPAM	15	MG	4/DAY-MAX QTY 120
OXAZEPAM	30	MG	4/DAY-MAX QTY 120
MEPROBAMATE	200	MG	4/DAY
MEPROBAMATE	400	MG	4/DAY
KLONOPIN	0.5	MG	3/DAY
CLONAZEPAM	0.5	MG	3/DAY
KLONOPIN	1	MG	3/DAY
CLONAZEPAM	1	MG	3/DAY
KLONOPIN	2	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

Product name	Strength		Utilization Edit
NEFAZODONE HCL	50	MG	2/DAY
NEFAZODONE HCL	100	MG	2/DAY
NEFAZODONE HCL	150	MG	2/DAY
NEFAZODONE HCL	200	MG	2/DAY
NEFAZODONE HCL	250	MG	2/DAY
CHLORDIAZEPOXIDE/AMITRIPTYLINE	5-12.5	MG	
CHLORDIAZEPOXIDE/AMITRIPTYLINE	10-25	MG	
AMYTAL SODIUM	500	MG	
BUTISOL SODIUM	30	MG	3/DAY
NEMBUTAL SODIUM	50	MG/ML	
PENTOBARBITAL SODIUM	50	MG/ML	
PENTOBARBITAL SODIUM	0		
SECONAL SODIUM	100	MG	
CHLORAL HYDRATE	0		
ESTAZOLAM	1	MG	1/DAY
ESTAZOLAM	2	MG	1/DAY
FLURAZEPAM HCL	15	MG	1/DAY
FLURAZEPAM HCL	30	MG	1/DAY
MIDAZOLAM HCL	2	MG/ML	
MIDAZOLAM HCL	2	MG/2ML	
MIDAZOLAM HCL	5	MG/5ML	
MIDAZOLAM HCL	10	MG/10ML	
MIDAZOLAM HCL	5	MG/ML	
MIDAZOLAM HCL	10	MG/2ML	
MIDAZOLAM HCL	5	MG/ML	
MIDAZOLAM HCL	25	MG/5ML	
MIDAZOLAM HCL	5	MG/ML	
MIDAZOLAM HCL	50	MG/10ML	
MIDAZOLAM HCL	5	MG/ML	
DORAL	15	MG	1/DAY
QUAZEPAM	15	MG	1/DAY
RESTORIL	7.5	MG	1/DAY
TEMAZEPAM	7.5	MG	1/DAY

Product name	Strength		Utilization Edit
RESTORIL	15	MG	1/DAY
TEMAZEPAM	15	MG	1/DAY
RESTORIL	22.5	MG	1/DAY
TEMAZEPAM	22.5	MG	1/DAY
RESTORIL	30	MG	1/DAY
TEMAZEPAM	30	MG	1/DAY
TRIAZOLAM	0.125	MG	1/DAY
HALCION	0.25	MG	1/DAY
TRIAZOLAM	0.25	MG	1/DAY
LUNESTA	1	MG	1/DAY
ESZOPICLONE	1	MG	1/DAY
LUNESTA	2	MG	1/DAY
ESZOPICLONE	2	MG	1/DAY
LUNESTA	3	MG	1/DAY
ESZOPICLONE	3	MG	1/DAY
SONATA	5	MG	2/DAY
ZALEPLON	5	MG	2/DAY
SONATA	10	MG	2/DAY
ZALEPLON	10	MG	2/DAY
AMBIEN	5	MG	1/DAY
ZOLPIDEM TARTRATE	5	MG	1/DAY
AMBIEN	10	MG	1/DAY
ZOLPIDEM TARTRATE	10	MG	1/DAY
AMBIEN CR	6.25	MG	1/DAY
ZOLPIDEM TARTRATE ER	6.25	MG	1/DAY
AMBIEN CR	12.5	MG	1/DAY
ZOLPIDEM TARTRATE ER	12.5	MG	1/DAY
INTERMEZZO	1.75	MG	1/DAY
ZOLPIDEM TARTRATE	1.75	MG	1/DAY
INTERMEZZO	3.5	MG	1/DAY
ZOLPIDEM TARTRATE	3.5	MG	1/DAY
EDLUAR	5	MG	1/DAY
EDLUAR	10	MG	1/DAY
ZOLPIMIST	5	MG/ACT	2 SPRAYS (0.25ML)/DAY

APPENDIX C – 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
pentobarbital	50 mg/mL	
secobarbital	100 mg	
zaleplon	5 mg	2/day
zaleplon	10 mg	2/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

Appendix D – 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
suvorexant	10 mg	1/day
suvorexant	15 mg	1/day
suvorexant	20 mg	1/day

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/17/2018	10/17/2018
Added Carisoprodol criteria	11/2018	11/2018
Annual Review – No changes	10/2019	10/2019
Annual Review – No changes	10/2020	10/2020
Updated for Benzo initiation and Annual review	09/2021	10/2021
Updated to align with OMPP and MHQAC approvals.	6/2022	4/2022

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to

recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.