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Chronic Use of Controlled Sedative/Hypnotic Agents

The DUR Commission recently reviewed pharmacy claims data identifying members using a controlled sedative/hypnotic agent on a chronic basis. Controlled sedative/hypnotic agents are generally recommended as short-term adjunctive therapy in the management of insomnia, and most are not FDA approved for long-term use. Long-term use may be associated with physical and/or psychological dependence.

Pharmacy claims for controlled sedative/hypnotic agents were reviewed to identify members with 90 or more days of medication from April through July 2021. There were 4,592 members that met these criteria.

FDA approved controlled sedative/hypnotics included in the review:

Estazolam 1 mg, 2 mg tablet	Begin with 1 mg orally at bedtime; some patients may require 2 mg nightly
Eszopiclone 1 mg, 2 mg, 3 mg tablet	Initial, 1 mg orally once daily immediately before bedtime; may increase to 2 mg or 3 mg/day orally if clinically indicated; maximum dose, 3 mg/day
Flurazepam 15 mg, 30 mg capsule	The recommended dose is 15 to 30 milligrams at bedtime. Dosage should be individualized. Efficacy has been maintained for up to 4 weeks of continuous therapy, but long-term treatment is not recommended.
Lemborexant 5 mg, 10 mg tablet	5 mg orally taken no more than once nightly, immediately prior to bed and with at least 7 hours remaining before planned time of awakening; may increase to 10 mg once nightly
Quazepam 15 mg tablet	7.5 mg orally at bedtime. The dose may be increased to 15 mg at bedtime if needed; use the lowest effective dose. If insomnia does not improve after 7 to 10 days of treatment, evaluate the patient for the presence of psychiatric or medical illness
Secobarbital 100 mg capsule	100 mg at bedtime; may lose effectiveness for sleep induction and maintenance after 2 weeks of use
Suvorexant 5 mg, 10 mg, 20 mg tablet	10 mg orally taken no more than once/night, within 30 minutes of bedtime and with at least 7 hours available prior to awakening; use lowest effective

	dose; maximum dose: 20 mg nightly; for all doses, take no more than once per night; use the lowest effective dose
Temazepam 7.5 mg, 15 mg, 22.5mg, 30 mg capsule	15 mg before retiring; 7.5 mg may be sufficient for some patients, while others may require 30 mg
Triazolam 0.125 mg, 0.25 mg tablet	0.25 mg orally at bedtime and may titrate to 0.5 mg in select patients who do not respond to the lower dosage; a lower initial dosage of 0.125 mg may be appropriate in some patients; maximum dose, 0.5 mg/day. Use for more than 3 weeks requires evaluation of the patient for primary psychiatric or medical condition. Prescriptions should be written for short-term use (7 to 10 days) and it should not be prescribed in quantities exceeding a 1-month supply
Zaleplon 5 mg, 10mg capsule	The recommended dose for the short-term treatment of insomnia is 10 mg at bedtime. A 5 mg dose may be used in low weight individuals. The dose may be increased to 20 mg if necessary; has been shown to be safe and effective for up to 35 nights
Zolpidem Tartrate 5 mg, 10 mg oral and SL tablet; 6.25 mg, 12.5 mg ER tablet; 5 mg/0.1 ml oral spray	Insomnia, short-term treatment: IR & SL tablets: 5 or 10 mg in men and 5 mg in women orally once daily as a single dose immediately before bedtime with at least 7 to 8 hours remain before planned awakening. Do not readminister during the same night. Individualize and use lowest effective dose; maximum dose, 10 mg/day ER tablets: 6.25 or 12.5 mg in men and 6.25 mg in women orally once daily as a single dose immediately before bedtime with at least 7 to 8 hours remain before planned awakening. Do not readminister during the same night. Individualize and use lowest effective dose; maximum dose, 12.5 mg/day Oral spray: 5 or 10 mg (1 or 2 sprays) directly into mouth over the tongue, immediately before bedtime [11]; the dose in women is 5 mg (1 spray); maximum dose, 10 mg/day All: if insomnia fails to respond to zolpidem within 7 to 10 days, evaluate patient for an underlying primary psychiatric or physical condition
Zolpidem Tartrate 1.75 mg, 3.5 mg SL tablet	Insomnia, characterized by difficulty returning to sleep after middle-of-the-night awakening: men: 3.5 mg SL once per night as needed; this is also the maximum dose; women: 1.75 mg SL once per night as needed; this is also the maximum dose

Based on this information, the DUR Commission made the following recommendations

- Implement a 7-day initial limit on all benzodiazepines for new users. The ProDUR point-of-sale (POS) edit would limit to an initial 7 days' supply for a benzodiazepine if the requested benzodiazepine is not found in pharmacy claims in the preceding 90 days. Exceptions to this edit include nasal and rectal diazepam, nasal midazolam and clobazam. Prior authorization (PA) would be required for use beyond the 7-day

allowance. The Commission will develop PA criteria for requests exceeding the initial limit at a future meeting and will be shared with interested parties for comment prior to implementation.

- Implement a cumulative quantity limit of 4 units per day across the benzodiazepine class for solid oral dosage forms.

Medicaid Statistics for Prescription Claims December 2021 through February 2022

	FFS	Amerigroup	Iowa Total Care
# Paid Claims	21,022	1,111,758	784,907
Total \$ Paid	\$2,375,607	\$118,541,721	\$79,777,205
Unique Users	3,728	173,760	128,674
Avg Cost/Rx	\$113.01	\$106.63	\$101.64
Top 5 Therapeutic Class by Prescription Count Therapeutic class taxonomy differs among each plan	Antidepressants – Selected SSRIs	Antidepressants	SSRIs
	Anticonvulsants	Antiasthmatic & Bronchodilator Agents	Anticonvulsants – Misc.
	Antipsychotics – Atypicals	Anticonvulsants	Sympathomimetics
	Antihypertensives-Central	ADHD/Anti-Narcolepsy	PPIs
	Antiasthmatic – Beta Adrenergics	Antihypertensives	NSAIDs
Top 5 Therapeutic Class by Paid Amount (pre-rebate) Therapeutic class taxonomy differs among each plan	Anticonvulsants	Antidiabetics	Insulin
	Muscular Dystrophy Agents	Antipsychotics/Antimanic Agents	Anti-TNF-alpha Monoclonal Antibodies
	Anti-Inflammatories, Non-NSAID	Analgesics – Anti-Inflammatory	Sympathomimetics
	Antipsychotics – Atypicals	Antiasthmatic & Bronchodilator Agents	Incretin Mimetic Agents (GLP-1 Receptor Agonists)
	Antidepressants – Selected SSRIs	Dermatologicals	Antipsychotics – Misc.
Top 5 Drugs by Prescription Count	Trazodone	Sertraline	Sertraline
	Clonidine	Omeprazole	Omeprazole
	Sertraline	Trazodone	Amoxicillin
	Escitalopram	Amoxicillin	Atorvastatin
	Omeprazole	Escitalopram	Trazodone
Top 5 Drugs by Paid Amount (pre-rebate)	Evrysdi	Humira (CF) Pen	Humira Pen
	Humira Pen	Vyvanse	Vyvanse
	Trikafta	Vraylar	Vraylar
	Biktarvy	Trulicity	Trulicity
	Invega Sustenna	Latuda	Trikafta