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Tapentadol Drug Use Evaluation

Recommendations

- Add tapentadol to the list of medications subject to the High Dose Opioid PA Criteria
- Apply quantity limits consistent with PA Criteria, package insert dosages, and tablet optimization
- Do not grandfather patients currently receiving tapentadol

Introduction

As addressed in previous Drug Use Evaluations (DUE), opioid analgesic misuse and abuse have generated significant concerns in the medical community, legislative bodies, and the media.[1,2] These DUEs did not address the use of tapentadol, a novel synthetic mu opioid receptor agonist with norepinephrine re-uptake inhibition (NRI). The efficacy of tapentadol has been demonstrated to be non-inferior to currently available opioids for the approved indications. The side effect profile is comparable to other mu opioid receptors, with slightly lower incidence of GI effects, but higher incidence of sympathetic stimulation. Unlike most opioids, tapentadol has a maximum daily dose due to NRI effects.[3,4]

Analysis

Based on clinical trials of tapentadol, equivalents doses of morphine are 0.24-0.36mg tapentadol to 1mg morphine.[3] When compare to oxycodone the range is 0.24-0.72mg tapentadol to 1mg of morphine equivalents.[5–7] These data suggest a reasonable conversion factor of 0.4 mg tapentadol to 1mg morphine, which is consistent with publically available conversion tools.[8] Table 1 lists quantity limits with morphine equivalents for each strength and formulation. Quantity limits also allow for gradual titration according to recommendations in the package inserts.[3,4]

Recent FFS pharmacy claims indicate 2 members with more than 6 prescriptions and only two members currently receiving Tapentadol. Based on this limited use, no grandfather of existing therapy is recommended.

Generic	Brand	Form	Strength (mg)	Daily Quantity Limit	High Dose PA Limit	Morphine Equivalents Daily for High Dose PA Limit	Comment
TAPENTADOL HCL	NUCYNTA	TABLET	50	6	6	120	tablet optimization Dosing Q4-6hr
TAPENTADOL HCL	NUCYNTA	TABLET	75	6	4	120	tablet optimization Dosing Q4-6hr
TAPENTADOL HCL	NUCYNTA	TABLET	100	6	3	120	Maximum Dose 600mg daily[3]
TAPENTADOL HCL	NUCYNTA ER	TAB ER 12H	50	2	6	120	BID dosing
TAPENTADOL HCL	NUCYNTA ER	TAB ER 12H	100	2	3	120	BID dosing
TAPENTADOL HCL	NUCYNTA ER	TAB ER 12H	150	2	2	120	BID dosing
TAPENTADOL HCL	NUCYNTA ER	TAB ER 12H	200	2	1	80	BID dosing
TAPENTADOL HCL	NUCYNTA ER	TAB ER 12H	250	2	1	100	Maximum Dose 500mg daily[4]

Table 1 – Recommended Quantity Limits for Tapentadol

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