

Criteria for Nonformulary Use of Propoxyphene

VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high-quality, cost-effective drug therapy. These criteria are not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations.

A summary of the literature review used to support the criteria for use of propoxyphene is available at <http://www.pbm.va.gov>.

Although propoxyphene is considered to be a weak opioid, it can cause deaths—often sudden deaths—related to drug overuse (e.g., taking more than prescribed doses), misuse, and moderate, accidental, and intentional overdoses. These deaths often, but not always, occurred when propoxyphene was taken concurrently with alcohol or other CNS depressants. Because of these drug-related deaths, unlike other opioids, propoxyphene has a Boxed Warning advising providers to avoid use in patients who are suicidal or addiction-prone.

Propoxyphene and its metabolite, norpropoxyphene, are cardiotoxic and neurotoxic. Drug and metabolite serum concentrations increase with repeated dosing and in renal or hepatic impairment.

VA Criteria for Use

Patients who meet any of the following exclusion criteria should NOT receive propoxyphene:	YES	NO
Current history of suicidal ideation, suicide attempt, or depression	<input type="checkbox"/>	<input type="checkbox"/>
History or propensity of drug overuse (e.g., taking more than prescribed doses), misuse, abuse, addiction/dependence, or diversion	<input type="checkbox"/>	<input type="checkbox"/>
Current diagnosis of alcohol abuse or dependence	<input type="checkbox"/>	<input type="checkbox"/>
Current or past history of seizures	<input type="checkbox"/>	<input type="checkbox"/>
Impairment of renal or hepatic function	<input type="checkbox"/>	<input type="checkbox"/>
<i>No specific recommendations exist for appropriate dosage adjustments in these situations.</i>		
More than 4 doses per day or greater than 390 mg per day of propoxyphene HCl (600 mg per day propoxyphene napsylate) is required for pain relief	<input type="checkbox"/>	<input type="checkbox"/>

Continued

Weigh Risks Versus Benefits and Use Caution

Use caution when prescribing propoxyphene in patients with the following characteristics:	YES	NO
Past history of suicidal ideation, suicide attempt, or depression or current or past history of emotional disturbances or other psychiatric disorder	<input type="checkbox"/>	<input type="checkbox"/>
Concurrent treatment with sedatives, tranquilizers, muscle relaxants, antidepressants, or other CNS-depressant drugs <i>Caution patients about additive CNS-depressant effects.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Excessive alcohol intake or distant history of alcohol abuse or dependence <i>Advise patients to limit their intake of alcohol, and caution them about additive CNS-depressant effects.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Pregnant or nursing	<input type="checkbox"/>	<input type="checkbox"/>
Use in the elderly (due to decreased metabolism) <i>Consider using less frequent dosing intervals.</i>	<input type="checkbox"/>	<input type="checkbox"/>
Current or past history of cardiac arrhythmias or prolonged conduction times on ECG (QRS interval)	<input type="checkbox"/>	<input type="checkbox"/>

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