

Pharmacy Director | Annual Budget Impact Model

Psychiatric (higher prevalence, higher agitation rate)

IGALMI™ (dexmedetomidine) sublingual film Pharmacy Cost-Estimator for Acute Treatment of Agitation Associated with Schizophrenia or Bipolar I or II Disorder <small>The safety and effectiveness of IGALMI has not been established beyond 24 hours from the first dose.</small>					
Population	Inputs	Schizophrenia	Inputs	Bipolar Disorder	
Emergency Department Volume	30,000	30,000	30,000	30,000	LEGEND: Editable Not Editable
Adults diagnosed with SCZ or BPD for all ED encounters	25.0%	7,500	25.0%	7,500	
Estimated rate of agitation					
presenting with agitation	52%	3,900	52%	3,900	
Estimate of population requiring medications					
% requiring medications	47%	1,833	47%	1,833	
% utilization	10%	183	10%	183	
Estimated costs of using Igalmi					
WAC price per dose of IGALMI	\$105.00	\$19,247	\$105.00	\$19,247	
		SCZ Basecase		BPD Basecase	

INDICATION

IGALMI is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. Limitations of Use: The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose.

IMPORTANT SAFETY INFORMATION

IGALMI is self-administered under the supervision of a healthcare provider. A healthcare provider should monitor vital signs and alertness after IGALMI administration to prevent falls and syncope. (See next page for additional safety information.)

Note: The Pharmacy Cost-Estimator tool is intended to provide an estimate of the potential annual pharmacy cost to use IGALMI based on ED volume. The tool does not include other potential medical costs or costs offsets. Research in this patient population is limited; thus, this tool was developed using multiple data sources, including published literature and claims data research.



Pharmacy Director | Annual Budget Impact Model



WARNINGS AND PRECAUTIONS

Hypotension, Orthostatic Hypotension, and Bradycardia: IGALMI causes dose-dependent hypotension, orthostatic hypotension, and bradycardia. In clinical studies with IGALMI, patients were excluded if they had treatment with alpha-1 noradrenergic blockers, benzodiazepines, other hypnotics or antipsychotic drugs four hours prior to study drug administration; had a history of syncope or syncopal attacks; SBP < 110 mmHg; DBP < 70 mmHg; HR < 55 beats per minute; or had evidence of hypovolemia or orthostatic hypotension. Because IGALMI decreases sympathetic nervous system activity, hypotension and/or bradycardia may be more pronounced in patients with hypovolemia, diabetes mellitus, or chronic hypertension, and in geriatric patients. Avoid use of IGALMI in patients with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope. After IGALMI administration, patients should be adequately hydrated and should sit or lie down until vital signs are within normal range. If a patient is unable to remain seated or lying down, precautions should be taken to reduce the risk of falls. Ensure that a patient is alert and not experiencing orthostatic hypotension or symptomatic hypotension prior to allowing them to resume ambulation.

QT Interval Prolongation: IGALMI prolongs the QT interval. Avoid use of IGALMI in patients at risk of torsades de pointes or sudden death, including those with known QT prolongation, a history of other arrhythmias, symptomatic bradycardia, hypokalemia, or hypomagnesemia, and in patients receiving other drugs known to prolong the QT interval.

Somnolence: IGALMI can cause somnolence. Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or operating hazardous machinery, for at least eight hours after taking IGALMI.

Risk of Withdrawal Reactions, Tolerance, and Tachyphylaxis: IGALMI was not studied for longer than 24 hours after the first dose. There may be a risk of physical dependence, a withdrawal syndrome, tolerance, and/or tachyphylaxis if IGALMI is used in a manner other than indicated.

(See next page for additional safety information.)



Pharmacy Director | Annual Budget Impact Model



ADVERSE REACTIONS

The most common adverse reactions (incidence $\geq 5\%$ and at least twice the rate of placebo) were somnolence, oral paresthesia or oral hypoesthesia, dizziness, dry mouth, hypotension, and orthostatic hypotension.

DRUG INTERACTIONS

Drugs That Prolong the QT Interval: Avoid use. Concomitant use of drugs that prolong the QT interval may add to the QT-prolonging effects of IGALMI and increase the risk of cardiac arrhythmia.

Anesthetics, Sedatives, Hypnotics, and Opioids: Concomitant use may cause enhanced CNS-depressant effects. Reduction in dosage of IGALMI or the concomitant medication should be considered.

USE IN SPECIFIC POPULATIONS

Hepatic Impairment and Geriatric Patients (≥ 65 years old): A lower dose is recommended in patients with hepatic impairment and geriatric patients. See the full Prescribing Information for the recommended dosage depending on the agitation severity.

Please see full [Prescribing Information](http://www.IGALMIHCP.com) at www.IGALMIHCP.com

