

Igalmi (dexmedetomidine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Igalmi (dexmedetomidine) sublingual film	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Igalmi (dexmedetomidine) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has been diagnosed with schizophrenia or bipolar I or II disorder; **AND**
- III. Individual is using for the acute treatment of agitation under the supervision of a healthcare provider.

Igalmi (dexmedetomidine) may not be approved for the following:

- I. Individuals with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope; **OR**
- II. Individuals using medications that increase the QT interval (including class 1A antiarrhythmics [including quinidine, procainamide] or class III antiarrhythmics [including amiodarone, sotalol], other antipsychotic agents [such as ziprasidone, chlorpromazine, thioridazine], antibiotics [including gatifloxacin, moxifloxacin]) and cannot discontinue the medication; **OR**
- III. Individuals at risk for torsades de pointes or sudden death, including those with known QT prolongation, history of cardiac arrhythmias, symptomatic bradycardia, hypokalemia or hypomagnesemia.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 10, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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