Original Effective Date: 07/27/2022
Current Effective Date: 09/28/2022
Last P&T Approval/Version: 07/27/2022
Next Review Due By: 07/2023
Policy Number: C23724-A

Igalmi (dexmedetomidine)

PRODUCTS AFFECTED

Igalmi (dexmedetomidine)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Acute agitation

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. ACUTE AGITATION:
   1. Documented diagnosis of schizophrenia, bipolar I or bipolar II disorder
      AND
   2. Documentation of trial/failure of or intolerance to ALL OF THE FOLLOWING: an injectable benzodiazapine, haloperidol, injectable olazapine, injectable ziprasidone. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.

CONTINUATION OF THERAPY: NA

DURATION OF APPROVAL:
Initial authorization: 1 dispense (maximum of 10 pouches of any ONE strength)
Continuation of Therapy: NA

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a behavioral health specialist [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY: maximum total daily dosage = 360 mcg (see dosing in OTHER CONSIDERATIONS) – One daily dose per dispense.
The safety and effectiveness of IGALMI have not been established beyond 24 hours from the first dose

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered. Igalmi (dexmedetomidine) should be 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

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Sublingual

DRUG CLASS:
Selective Alpha2-Adrenoreceptor Agonist Sedatives

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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Igalmi (dexmedetomidine) are considered experimental/investigational and

therefore, will follow Molina's Off- Label policy. Contraindications to Igalmi (dexmedetomidine) include:

OTHER SPECIAL CONSIDERATIONS:

Patient Population	Agitation Severity	Initial Dose*	Optional 2nd/3rd Doses*	Maximum Recommended Total Daily Dosage
Adults	Mild or Moderate	120 mcg	60 mcg	240 mcg
	Severe	180 mcg	90 mcg	360 mcg
Patients with Mild or Moderate Hepatic Impairment**	Mild or Moderate	90 mcg	60 mcg	210 mcg
	Severe	120 mcg	60 mcg	240 mcg
Patients with Severe Hepatic Impairment**	Mild or Moderate	60 mcg	60 mcg	180 mcg
	Severe	90 mcg	60 mcg	210 mcg
Geriatric Patients (≥ 65 years old)	Mild, Moderate, or Severe	120 mcg	60 mcg	240 mcg

* IGALMI 120 mcg and 180 mcg dosage strengths may be cut in half to obtain the 60 mcg and 90 mcg doses, respectively *[see Dosage and Administration (2.3)]*.

** Hepatic impairment: Mild (Child-Pugh Class A); Moderate (Child-Pugh Class B); Severe (Child-Pugh Class C)

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Igalmi 120mcg

Igalmi 180 mcg

REFERENCES

1. Igalmi (dexmedetomidine) [prescribing information]. New Haven, CT: BioXcel Therapeutics Inc; April 2022.

SUMMARY OF REVIEW/REVISIONS	DATE
NEW CRITERIA CREATION	Q3 2022