Original Effective Date: 07/27/2022
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Last P&T Approval/Version: 01/25/2023
Next Review Due By: 01/2024
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 benzodiazepine, haloperidol, injectable olanzapine, injectable ziprasidone. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required [DOCUMENTATION REQUIRED].
      AND
   3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA

labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Igalmi (dexmedetomidine) include: use in patients with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope, use in patients with risk factors for prolonged QT interval, concomitant use of drugs that prolong the QT interval.]
AND

4. Prescriber attests they will supervise and monitor the member's vital signs and alertness after administration

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 with initial request]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
Maximum total daily dosage = 360 mcg (see APPENDIX) – 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.

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 has not been established beyond 24 hours from the first dose.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

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)

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: use in patients with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope, use in patients with risk factors for prolonged QT interval, concomitant use of drugs that prolong the QT interval.

OTHER SPECIAL CONSIDERATIONS:
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.

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 FILM 120MCG
Igalmi FILM 180MCG

REFERENCES

1. Igalmi (dexmedetomidine) [prescribing information]. New Haven, CT: BioXcel Therapeutics Inc; July 2022.
2. American Psychiatric Association. (2020). The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia. doi:10.1176/appi.books.9780890424841
3. Practice guideline for the treatment of patients with bipolar disorder Second edition. (n.d.). APA Practice Guidelines for the Treatment of Psychiatric Disorders: Comprehensive Guidelines and Guideline Watches. doi:10.1176/appi.books.9780890423363.50051

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Prescriber Requirements Quantity Place of Administration Contraindications/Exclusions/Discontinuation Available Dosage Forms References	Q1 2023
NEW CRITERIA CREATION	Q3 2022