Original Effective Date: 07/27/2022
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Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ACUTE AGITATION:
   1. Documented diagnosis of schizophrenia, bipolar I or bipolar II disorder
      AND
   2. Documentation of trial/failure of or serious side effect 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: avoid use in patients with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope, avoid use in patients with risk factors for prolonged QT interval, avoid 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:

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information

State Marketplace

Nevada (Source: Nevada Legislature)

"Chapter 689A of Nevada Revised Statutes (NRS) is hereby amended by adding thereto a new section to read as follows:

1. A policy of health insurance which provides coverage for prescription drugs must not require an insured to submit to a step therapy protocol before covering a drug approved by the Food and Drug Administration that is prescribed to treat a psychiatric condition of the insured, if:
    a. The drug has been approved by the Food and Drug Administration with indications for the psychiatric condition of the insured or the use of the drug to treat that psychiatric condition is otherwise supported by medical or scientific evidence;
    b. The drug is prescribed by:
        i. A psychiatrist
        ii. A physician assistant under the supervision of a psychiatrist;
        iii. An advanced practice registered nurse who has the psychiatric training and experience prescribed by the State Board of Nursing pursuant to NRS 632.120; or
        iv. A primary care provider that is providing care to an insured in consultation with a practitioner listed in subparagraph (1), (2) or (3), if the closest practitioner listed in subparagraph (1), (2) or (3) who participates in the network plan of the insurer is located 60 miles or more from the residence of the insured; and
    c. The practitioner listed in paragraph (b) who prescribed the drug knows, based on the medical history of the insured, or reasonably expects each alternative drug that is required to be used earlier in the step therapy protocol to be ineffective at treating the psychiatric condition…
3. As used in this section:
    c. *'Step therapy protocol' means a procedure that requires an insured to use a prescription drug or sequence of prescription drugs other than a drug that a practitioner recommends for treatment of a psychiatric condition of the insured before his or her policy of health insurance provides coverage for the recommended drug*."

Molina Reviewer Note: Medical necessity review for a psychiatric condition cannot require trial of other medications first. This is applicable to formulary medications that require prior authorization and non-formulary medications and is not limited to only medications designated 'ST'. If the requested drug is a brand name and the generic is on formulary, request can be reviewed for specific medical reason generic cannot be used.

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: avoid use in patients with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope, avoid use in patients with risk factors for prolonged QT interval, avoid 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
J1105	Dexmedetomidine, oral, 1 mcg

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 Coding/Billing Information	Q1 2024
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