

Policy: MBP 265.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Igalmi (dexmedetomidine)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:

Igalmi (dexmedetomidine)

II. Purpose/Objective:

To provide a policy of coverage regarding Igalmi (dexmedetomidine).

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

DESCRIPTION: Igalmi (dexmedetomidine) is an alpha-2 adrenergic receptor agonist. The mechanism of action of Igalmi in the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder is thought to be due to activation of presynaptic alpha-2 adrenergic receptors in the brainstem, resulting in inhibition of norepinephrine release.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Igalmi (dexmedetomidine) will be considered medically necessary for the commercial, exchange, CHIP, and Medicare lines of business when all of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of schizophrenia OR bipolar I or II disorder **AND**
- Medical record documentation that Igalmi will be used to for the acute treatment of agitation **AND**
- Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the acute use of an antipsychotic and a benzodiazepine for the management of agitation **AND**
- Medical record documentation that Igalmi will be administered under the supervision of a healthcare provider

AUTHORIZATION DURATION: 7 days

QUANTITY LIMIT: 2 films per fill

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Igalmi [prescribing information]. New Haven, CT: BioXcel Therapeutics Inc; April 2022.
2. Roppolo, LP, Morris DW, Khan F, et al. Improving the management of acutely agitated patients in the emergency department through implementation of Project BETA (Best Practices in the Evaluation and Treatment of Agitation). J Am Coll Emerg Physicians Open. 2020;1(5):898-907 [cited 2023 Dec 26]. Available from: <https://onlinelibrary.wiley.com/doi/10.1002/emp2.12138>

This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/19/22

Revised: 7/12/23 (LOB carve out, Medicaid business segment), 12/28/23 (references added), 6/20/25 (LOB table, taglines, removed Medicaid business segment)

Reviewed: 6/28/24

MA UM Committee approval: 12/31/23, 12/31/24, 9/10/25