

## PHARMACY COVERAGE GUIDELINE

### DIBENZYLINE® (phenoxybenzamine) Phenoxybenzamine

#### **This Pharmacy Coverage Guideline (PCG):**

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

#### **Scope**

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

#### **Instructions & Guidance**

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy). You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com).

#### **Criteria:**

- **Criteria for initial therapy:** Dibenzyline (phenoxybenzamine) or phenoxybenzamine is considered **medically necessary** and will be approved when **ALL** the following criteria are met:
1. Individual is 18 years of age or older
  2. Individual has a confirmed diagnosis of **ONE** of the following:
    - a. Pheochromocytoma with episodes of headache, sweating, and tachycardia with or without paroxysmal hypertension
    - b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

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3. **For brand Dibenzyline only:** Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for **generic oral phenoxybenzamine** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
4. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **ALL** the following:
  - a. Doxazosin
  - b. Prazosin
  - c. Terazosin

**Initial approval duration:** 6 months

- **Criteria for continuation of coverage (renewal request):** Dibenzyline (phenoxybenzamine) or phenoxybenzamine is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

1. Individual's condition has responded while on therapy with response defined as the following:
  - a. Blood pressure is controlled
  - b. No significant sweating, tachycardia, and episodic headaches
2. Individual has been adherent with the medication
3. **For brand Dibenzyline only:** Individual has failure, contraindication per FDA label, intolerance, or is not a candidate for **generic oral phenoxybenzamine** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] ([see Definitions section](#))
4. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
  - a. Significant episodes of postural hypotension
  - b. Episodes of significant tachycardia
  - c. Significant episodes of dizziness or fainting

**Renewal duration:** 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

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#### **Description:**

Phenoxybenzamine is a long-acting, adrenergic, *alpha*-receptor-blocking agent, is indicated in the treatment of pheochromocytoma, to control episodes of hypertension and sweating. The long-acting alpha-blockade produces and maintains a chemical sympathectomy. It also increases blood flow to the skin, mucosa, and abdominal viscera, and lowers both supine and erect blood pressures.

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#### **Definitions:**

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting  
[MedWatch Forms for FDA Safety Reporting | FDA](#)

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#### **Resources:**

Dibenzylamine (phenoxybenzamine) product information, revised by Concordia Pharmaceuticals Inc. 04-2020. Available at DailyMed  
<http://dailymed.nlm.nih.gov>. Accessed February 27, 2024.

Phenoxybenzamine product information, revised by Par Pharmaceutical, Inc. 05-2017. Available at DailyMed  
<http://dailymed.nlm.nih.gov>. Accessed February 27, 2024.

Young WF, Kebebew E. Treatment of pheochromocytoma in adults. In: UpToDate, Nieman LK, Carty SE, Martin KA, Chen W (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through January 2024. Topic last updated February 12, 2021. Accessed February 27, 2024.

Young WF. Clinical presentation and diagnosis of pheochromocytoma. In: UpToDate, Nieman LK, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Literature current through January 2024. Topic last updated October 03, 2022. Accessed February 27, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Neuroendocrine and Adrenal Tumors Version 1.2023 – Updated August 02, 2023. Available at <https://www.nccn.org>. Accessed February 27, 2024.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.