Pharmacy Policy Bulletin

**Title:** Phenoxybenzamine (Dibenzyline®)

**Policy #:** Rx.01.190

***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

**Intent:**

The intent of this policy is to communicate the medical necessity criteria for **phenoxybenzamine (Dibenzyline®)** as provided under the member's prescription drug benefit.

**Description:**

Pheochromocytomas are rare catecholamine secreting tumors, usually located within the adrenal glands, which may result in life-threatening hypertension or arrhythmias. Pheochromocytomas reportedly occur in 0.05-0.2% of hypertensive individuals. This is likely an underestimate, since some patients are asymptomatic. Approximately 10% of pheochromocytomas are discovered incidentally and 50% had diagnosis made on autopsy.

Unlike catecholamine release from healthy adrenal tissue, catecholamine release from pheochromocytomas is not regulated and the triggers for their release are unclear. Additionally, most pheochromocytomas predominantly release norepinephrine compared to predominantly epinephrine release from healthy adrenal tissue.

Surgical resection is the treatment of choice, usually resulting in cure of the hypertension. Medical therapy is used preoperatively, for hypertensive crises, and as primary therapy for individuals with metastatic pheochromacytomas. Alpha adrenergic blockade is the cornerstone of pharmacologic therapy for pheochromocytomas. In the perioperative setting, phenoxybenzamine is initiated 10-14 days prior to surgery, in conjunction with volume expansion. Beta blockade is initiated only after adequate alpha blockade has been achieved. Selective alpha 1 blocking agents (doxazosin, terazosin, prazosin) may be used when long term therapy is required, but are not recommended for the preoperative management.

Phenoxybenzamine is a long acting alpha adrenergic receptor antagonist, which produces and maintains a "chemical sympathectomy" when orally administered. Phenoxybenzamine (Dibenzyline®) is indicated in the treatment of pheochromocytoma, to control episodes of hypertension and sweating.

**Policy:**

**INITIAL CRITERIA**: Phenoxybenzamine (Dibenzyline®) is approved when there is a diagnosis of pheochromocytoma

Initial Authorization duration: 6 months

**REAUTHORIZATION CRITERIA**: Phenoxybenzamine (Dibenzyline®) is re-approved when both of the following are met:

1. Documentation of positive clinical response; and
2. Yearly evaluation by prescriber for long-term use

Reauthorization duration: 12 months

**Black Box Warning as shown in the drug Prescribing Information:**

N/A

**Guidelines:**

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**

Blake MA. Pheochromocytoma. Available from:http://emedicine.medscape.com/article/124059-overview. Accessed September 30, 2021.

Dibenzyline® (phenoxybenzamine) [package insert]. St. Michael, Barbados. Concordia Pharmaceuticals. Dec 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=8852dd44-098c-4d99-88e0-a092a8e08e11&type=display. Accessed September 30, 2021.

**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

| Brand name | Generic name |
|---|---|
| Dibenzyline® | phenoxybenzamine |

**Cross References:**

Off-Label Use Rx. 01.33

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| **Policy Version Number:** | 6.00 |
| **P&T Approval Date:** | September 23, 2021 |
| **Policy Effective Date:** | January 01, 2022 |
| **Next Required Review Date:** | September 23, 2022 |