Pharmacy Policy Bulletin: J-0224 Dibenzyline (phenoxybenzamine) – Commercial and Healthcare Reform	
Number: J-0224	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)** **1.** Other Managed Drugs = Yes w/ Prior Authorization **Healthcare Reform**: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0224-009	**Original Date:** 05/01/2019
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Dibenzyline (phenoxybenzamine)
FDA-Approved Indication(s):	• Treatment of pheochromocytoma, to control episodes of hypertension and sweating.

Background:	• Dibenzyline is a long-acting, adrenergic, alpha-receptor blocking agent that causes muscle relaxation and widening of blood vessels. This increases blood flow to the skin, mucosa, and abdominal viscera, thereby lowering blood pressure. • Pheochromocytoma is the result of catecholamine secreting tumors present in the adrenal glands. Symptoms include high blood pressure, heavy sweating, headache, tachycardia, pallor, and dyspnea. It is estimated that the annual incidence of pheochromocytoma is approximately 0.8 per 100,000 person-years. The primary treatment for a pheochromocytoma is surgical removal of the catecholamine secreting tumor. Before surgery, specific blood pressure medications that block high-adrenaline hormones may be prescribed to lower the risk of developing dangerously high blood pressure during surgery. • Long-acting, selective, alpha-adrenergic antagonists increase blood flow to the mucosa and abdominal viscera. This lowers blood pressure,increases norepinephrine turnover, and releases neurotransmitters. • For the diagnosis of pheochromocytoma, the role of functional imaging is evolving. It is unclear what the preferred role of functional imaging should be in pheochromocytoma. Functional imaging such as computed tomography (CT) scans may be useful to localize a tumor after a biochemical diagnosis. • There is compelling evidence that measurements of plasma free or urinary fractionated metanephrines are superior to other tests of catecholamine excess for diagnosis. • Prescribing considerations:

	○ Case reports of carcinoma in humans after long-term treatment with Dibenzyline have been reported; therefore, long-term use is not recommended. ○ Dibenzyline is not recommended in conditions where a fall in blood pressure may be undesirable. ○ If tachycardia is excessive, it may be necessary to use a beta-blocking agent concomitantly.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Dibenzyline (phenoxybenzamine) may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of pheochromocytoma (ICD-10: C74.10) defined by one (1) of the following **(1. or 2.)**:

1. Elevated metanephrines in plasma or urine as defined by **(a. or b.)**:

a. Plasma fractionated metanephrines **(i. or ii.)**:

i. Normetanephrines > 0.6 nmol/L

ii. Metanephrine > 0.3 nmol/L

b. 24-hour urine fractionated metanephrines and catecholamines **(i. through v.)**:

i. Normetanephrine > 900 mcg/24 hours

ii. Metanephrine > 400 mcg/24 hours

iii. Norepinephrine > 170 mcg/24 hours

iv. Epinephrine > 35 mcg/24 hours

v. Dopamine > 700 mcg/24 hours

2. Tumor evidence from computed tomography (CT) scan or magnetic resonance imaging (MRI).

C. The member is experiencing excessive sweating and hypertension.

D. The member has experienced therapeutic failure to or intolerance to one (1) of the following plan-preferred products, or all are contraindicated **(1., 2., or 3.)**:

1. doxazosin

2. prazosin

3. terazosin

II. Reauthorization

When a benefit, reauthorization of Dibenzyline (phenoxybenzamine) may be approved when one (1) of the following criteria are met **(A. or B.)**:

A. The member experienced an incomplete response to tumor resection.

B. The member's tumor is unresectable.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial and HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Dibenzyline [package insert]. Dublin, Ireland: Amdipharm Limited; April 2020.
2. Mayo Clinic. Diseases and Conditions: Pheochromocytoma. Available at: https://www.mayoclinic.org/diseases-conditions/pheochromocytoma/symptoms-causes/syc-20355367. Accessed April 30, 2025.
3. Lenders JWM, Duh QY, Eisenhofer G. Pheochromocytoma and paraganglioma: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2014;99(6):1915-1942.
4. Lenders JWM, Pacak K, Walther MM, et al. Biochemical Diagnosis of Pheochromocytoma: Which Test Is Best? *JAMA*. 2002;287(11):1427–1434.
5. Sawka AM, Jaeschke R, Singh RJ, Young WF Jr. A comparison of biochemical tests for pheochromocytoma: measurement of fractionated plasma metanephrines compared with the combination of 24-hour urinary metanephrines and catecholamines. *J Clin Endocrinol Metab.* 2003 Feb;88(2):553-8.
6. Lenders JW, Keiser HR, Goldstein DS, et al. Plasma metanephrines in the diagnosis of pheochromocytoma. *Ann Intern Med*. 1995 Jul 15;123(2):101-9.