

# Drug Policy

<b>Policy:</b>	<b>Pheochromocytoma Prior Authorization</b> <b>Metyrosine capsules (Demser®, generics - Bausch Health, generics)</b> <b>Phenoxybenzamine capsules (Dibenzylin® - WellSpring Pharmaceuticals, generic)</b>	<b>Annual Review Date: 04/18/2024</b>  <b>Last Revised Date: 04/18/2024</b>
----------------	---	---

## OVERVIEW

Metyrosine capsules, a tyrosine hydroxylase inhibitor, is indicated for the treatment of patients with pheochromocytoma for preoperative preparation of patients for surgery; management of patients when surgery is contraindicated; and chronic treatment of patients with malignant pheochromocytoma.

Phenoxybenzamine capsules, a long-acting, adrenergic, alpha-receptor blocking agent, is indicated for the treatment of pheochromocytoma to control episodes of hypertension and sweating. If tachycardia is excessive, it may be necessary to use a beta-blocking agent concomitantly.

## POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of metyrosine and phenoxybenzamine. Due to the specialized skills required for evaluation and diagnosis of patients treated with metyrosine and phenoxybenzamine, as well as the monitoring required for AEs and long-term efficacy, approval requires these agents to be prescribed by or in consultation with a physician who specializes in the condition being treated.

## Recommended Authorization Criteria

- I. Coverage of phenoxybenzamine is recommended in those who meet the following criteria:

### FDA-Approved Indications

#### 1. Pheochromocytoma.

Initial therapy: Approve phenoxybenzamine for 3 months if the patient meets the following criteria (A and B):

- A) The agent is prescribed by, or in consultation with, an endocrinologist or a prescriber who specializes in the management of pheochromocytoma; AND
- B) The patient has a surgical resection planned, has a contraindication to surgery, or has malignant pheochromocytoma; AND
- C) The patient is using the requested medication to control sweating and hypertension associated with pheochromocytoma.

Patient is currently receiving phenoxybenzamine or has received phenoxybenzamine in the past. Approve for 1 year if phenoxybenzamine is prescribed by, or in consultation with, an endocrinologist or a prescriber who specializes in the management of pheochromocytoma and the member's condition has improved or stabilized while on therapy.

# Drug Policy

## **Initial Approval/ Extended Approval.**

- A) *Initial Approval:* 3 months (90 days)
- B) *Extended Approval:* 1 year (365 days)

II. Coverage of metirosine is recommended in those who meet the following criteria:

### **FDA-Approved Indications**

#### **1. Pheochromocytoma.**

Initial therapy. Approve metirosine for 3 months if the patient meets all of the following criteria (A, B, C and D)

- A) The patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin); AND
- B) The patient has tried phenoxybenzamine (brand or generic); AND
- C) Metyrosine is prescribed by, or in consultation with, an endocrinologist or a prescriber who specializes in the management of pheochromocytoma; AND
- D) The patient has a surgical resection planned, has a contraindication to surgery, or has chronic malignant pheochromocytoma; AND
- E) If the request is for brand Demser, the patient has tried or experienced intolerance to generic metirosine.

Patient is currently receiving metirosine or has received metirosine in the past. Approve for 1 year if metirosine is prescribed by, or in consultation with, an endocrinologist or a prescriber who specializes in the management of pheochromocytoma and the member's condition has improved or stabilized while on therapy.

## **Initial Approval/ Extended Approval.**

- A) *Initial Approval:* 3 months (90 days)
- B) *Extended Approval:* 1 year (365 days)

---

### **Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

### **REFERENCES**

1. Demser® capsules [prescribing information]. Bridgewater, NJ: Bausch Health; July 2020.
2. Dibenzyline® capsules [prescribing information]. St. Michael, Barbados: Concordia Pharmaceuticals; August 2020.

---

This document is subject to the disclaimer found at <https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx> and is subject to change. <https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx>

# Drug Policy

3. Lenders JWM, Duh QY, Eisenhofer G, et al. Pheochromocytoma and paraganglioma: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2014;99(6):1915-1942.
4. Fishbein L. Pheochromocytoma and paraganglioma: genetics, diagnosis and treatment. *Hematol Oncol Clin N Am.* 2016;30:135-150.
5. Hodin R, Lubitz C, Phitayakorn R, Stephen A. Diagnosis and management of pheochromocytoma. *Curr Prob Surg.* 2014;51(4):151-187.
6. Van der Zee PA, De Boer A. Pheochromocytoma: a review on preoperative treatment with phenoxybenzamine or doxazosin. *Neth J Med.* 2014;72(4):190-201.
7. Lenders JWM, Eisenhofer G. Update on modern management of pheochromocytoma and paraganglioma. *Endocrinol Metab (Seoul).* 2017;32(2):152-161.
8. Phentolamine injection. Bedford, OH: Bedford Laboratories; May 1999.
9. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 2.2020 – July 24, 2020) © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 20, 2020.
10. Phenoxybenzamine hydrochloride. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 28 February 2024. Accessed on 18 April 2024.
11. Metyrosine. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 12 December 2023. Accessed on 18 April 2024.
12. Phenoxybenzamine. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: <http://www.online.lexi.com>. Last updated 11 April 2024. Accessed on 18 April 2024.
13. Metyrosine. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: <http://www.online.lexi.com>. Last updated 24 February 2024.