



Policy:	Pheochromocytoma Prior Authorization	Annual Review Date: 04/17/2025
	Metyrosine capsules (Demser®, generics - Bausch Health, generics) Phenoxybenzamine capsules (Dibenzyline® - WellSpring Pharmaceuticals, generic)	Last Revised Date: 04/17/2025

OVERVIEW

Metyrosine capsules, a tyrosine hydroxylate 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.

<u>Initial therapy:</u> 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.

<u>Patient is currently receiving phenoxybenzamine</u>. 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.

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Initial Approval/ Extended Approval.

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

II. Coverage of <u>metyrosine</u> is recommended in those who meet the following criteria:

FDA-Approved Indications

1. Pheochromocytoma.

<u>Initial therapy</u>. Approve metyrosine 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 metyrosine *

<u>Patient is currently receiving metyrosine</u>. Approve for 1 year if metyrosine 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 2021.
- 2. Dibenzyline® capsules [prescribing information]. St. Michael, Barbados: Concordia Pharmaceuticals; August 2021.

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