



**Medication Policy Manual**

**Policy No:** dru405

**Topic:** Demser®, metyrosine

**Date of Origin:** June 12, 2015

**Committee Approval Date:** June 9, 2017

**Next Review Date:** March 2018

**Effective Date:** July 1, 2017

### **IMPORTANT REMINDER**

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

### **Description**

Metyrosine (Demser) is a self-administered medication for the management of hypertension in patients with pheochromocytoma. It inhibits tyrosine hydroxylase, resulting in decreased levels of catecholamines.

## Policy/Criteria

- I. Most contracts require prior authorization approval of metyrosine prior to coverage. Metyrosine may be considered medically necessary when criteria A and B below are met.
  - A. Documentation of a diagnosis of pheochromocytoma when established by or in consultation with a specialist in endocrinology.

**AND**

  - B. Treatment with an alpha blocker (such as phenoxybenzamine, prazosin, terazosin, or doxazosin) in combination with a beta blocker (such as propranolol, metoprolol, or atenolol) was ineffective, not tolerated, or is contraindicated.
- II. Administration, Quantity Limitations, and Authorization Period
  - A. OmedaRx considers metyrosine to be a self-administered medication.
  - B. When prior authorization is approved, metyrosine may be authorized in quantities up to 480 capsules per month.
- III. Metyrosine is considered investigational when used for all other conditions, including but not limited to:
  - A. Bipolar disorder
  - B. Schizophrenia

## Position Statement

- Metyrosine is a catecholamine-depleting agent used in the management of hypertension in patients with pheochromocytoma. [2]
- Pheochromocytoma is a rare neuroendocrine tumor that secretes catecholamines causing hypertension, headache, and sweating.
- Standard of care is surgical resection. [1]
- Prior to surgery and in patients where surgery is contraindicated, hypertension is managed by a variety of medications, including, but not limited to alpha blockers, beta blockers, and metyrosine. [1]
- There is no evidence that any hypertension management method in patients with pheochromocytoma is safer or more effective than another. Different approaches have not been compared in randomized controlled trials.
- The safety and efficacy of metyrosine in conditions other than pheochromocytoma have not been established.

## *Dosing* [2]

- Metyrosine is orally administered four times daily up to a maximum dosage of 4 grams per day.
- The safety and efficacy of higher doses have not been established.

<b>Cross References</b>
None

### **References**

1. Lenders JW, Duh QY, Eisenhofer G, Gimenez-Roqueplo AP, Grebe SK, Murad MH, Naruse M, Pacak K, Young WF Jr, Endocrine Society. Pheochromocytoma and paraganglioma: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2014 Jun;99(6):1915-42.
2. Demser [prescribing information]. Hunt Valley, MD: Aton Pharma; February 2010.

### *Revision History*

<b>Revision Date</b>	<b>Revision Summary</b>
06/09/2017	No criteria changes with this annual update.
06/10/2016	No criteria changes with this annual update.