Reference number(s)
6346-A

SPECIALTY GUIDELINE MANAGEMENT

DEMSER (metyrosine)
metyrosine (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Demser (metyrosine) is indicated in the treatment of patients with pheochromocytoma for:
1. Preoperative preparation of patients for surgery
2. Management of patients when surgery is contraindicated
3. Chronic treatment of patients with malignant pheochromocytoma

Demser (metyrosine) is not recommended for the control of essential hypertension.

B. Compendial Use
For pheochromocytoma/paraganglioma: may be used in combination with alpha blockade with or without dihydropyridine calcium channel blockade and/or beta blockade as medical preparation for primary treatment.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Pheochromocytoma/Paraganglioma
Authorization of 12 months may be granted for treatment of pheochromocytoma/paraganglioma when the member has experienced an inadequate treatment response, intolerance, or has a contraindication to an alpha-adrenergic antagonist (e.g., terazosin, doxazosin, prazosin, phenoxybenzamine) and any of the following criteria are met:
A. The requested agent will be used for preoperative preparation for surgery
B. The requested agent will be used for management when surgery is contraindicated
C. The requested agent will be used for chronic treatment for malignant pheochromocytoma

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II who have improvement in symptoms (e.g., blood pressure, heart rate, headaches, sweating, anxiety) and no unacceptable toxicity while on the current regimen.

IV. REFERENCES

1. Demser [package insert]. Bridgewater, NJ: Bausch Health US, LLC.; July 2021.
2. metyrosine [package insert]. Bridgewater, NJ. Amneal Pharmaceuticals LLC.; November 2020.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 24, 2024.
4. The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors Version 1.2023. National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 24, 2024.