

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Macrilen (macimorelin)
BILLING CODE	J8499
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Macrilen is a growth hormone (GH) secretagogue receptor agonist initially approved by the FDA in 2017. It is indicated for the diagnosis of adult growth hormone deficiency (AGHD) and is the first and only FDA-approved oral test for AGHD diagnosis. The efficacy of Macrilen was established in a randomized, open-label, single-dose, cross-over study. Macrilen was compared to the insulin tolerance test (ITT) in a head to head trial with 140 adults where the overall diagnostic accuracy of Macrilen was comparable to the ITT.

Macrilen (macimorelin) will be considered for coverage when the following criteria are met:

Diagnostic Use for Growth Hormone Deficiency

For **initial** authorization:

1. Member is age 18 years or older;
2. Medication must be prescribed by an endocrinologist;
3. Member's weight is documented on chart notes and member's BMI is $\leq 40 \text{ kg/m}^2$; AND
4. Member must have documentation of a contraindication or intolerance to **both** the insulin tolerance test and glucagon stimulation test.
5. **Dosage allowed/Quantity limit:** 0.5 mg/kg as single dose.
Quantity Limit: 1 pouch for weight $\leq 120 \text{ kg}$
2 pouches for weight $>120 \text{ kg}$

If all the above requirements are met, the medication will be approved for 30 days and will not be reauthorized.

CareSource considers Macrilen (macimorelin) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/20/2018	New policy for Macrilen created.
11/08/2022	Annual Review. Transferred to new template. Updated references. Updated the preferred test to ITT and GST. Added OAC reference.

References:

1. Macrilen [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; July 2021.
2. Yeun KC, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Growth Hormone Deficiency in Adults and Patients Transitioning from Pediatric to Adult Care. AACE 2019 Guidelines. 2019; 25(11):1191-1232.

3. Garcia JM, et al. Sensitivity and specificity of the macimorelin test for diagnosis of AGHD. *Endocr Connect*. 2021 Jan;10(1):76-83.
4. Garcia JM et al., Macimorelin as a Diagnostic Test for Adult GH Deficiency. *J Clin Endocrinol Metab*. 2018 May 31.
5. Diagnosis of growth hormone deficiency in childhood. *Curr Opin Endocrinol Diabetes Obes*. 2012;19(1):47-52.
6. Ohio Administrative Code. (2022, February 23). 5160-1-01 (C) Medicaid medical necessity: definitions and principles. Retrieved February 22 2023 from codes.ohio.gov.
7. Ohio Administrative Code. (2022, July 18). 5160-26-03 Managed care: covered services. Retrieved February 22, 2023 from codes.ohio.gov.
8. Ohio Administrative Code. (2020, January 1). 5160-9-03 Pharmacy services: covered drugs and associated limitations. Retrieved February 22, 2023 from codes.ohio.gov.

Effective date: 04/01/2023

Revised date: 11/08/2022