

Coverage of any medical intervention discussed in a Prevea360 Health Plan medical policy is subject to the limitations and exclusions outlined in the member's benefit certificate or summary plan description (SPD) and to applicable state and/or federal laws.

Gastric Electrical Stimulation (GES)

MP9463

Covered Service: Yes

Prior Authorization Required: No

Additional Information: The criteria in this policy do not apply to those devices which have been granted a humanitarian device exemption (HDE) by the FDA, which are considered medically necessary when all FDA-required criteria are met.

For a current list of HDE approved devices, refer to the FDA HDE database at: [Listing of CDRH Humanitarian Device Exemptions | FDA](#)

Prevea360 Health Plan Medical Policy:

- 1.0 Gastric electrical stimulation (Enterra® Therapy System) **does not require** prior authorization through the Health Services Division and is considered medically necessary for treating the following conditions in accordance with the U.S. Food and Drug Administration (FDA) section regarding FDA labeling and Humanitarian Device Exemption (HDE) for gastric electrical stimulation:
 - 1.1 Refractory diabetic gastroparesis that has failed other therapies
 - 1.2 Chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when used according to U.S. Food and Drug Administration (FDA) labeled indications.
- 2.0 Gastric electrical stimulation is considered experimental and investigational and therefore not medically necessary for all other indications, including diabetes mellitus in individuals without gastroparesis.

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	Committee/Source	Date(s)
Document Created:	Medical Policy Committee/Quality and Care Management Division	July 20, 2016
Revised:	Medical Policy Committee/Health Services Division	August 15, 2018
	Medical Policy Committee/Health Services Division	July 17, 2019
	Medical Policy Committee/Health Services Division	July 21, 2021
	Medical Policy Committee/Health Services Division	June 15, 2022
	Medical Policy Committee/Health Services Division	July 19, 2023
Reviewed:	Medical Policy Committee/Quality and Care Management Division	July 19, 2017
	Medical Policy Committee/Health Services Division	August 15, 2018
	Medical Policy Committee/Health Services Division	July 17, 2019
	Medical Policy Committee/Health Services Division	July 15, 2020
	Medical Policy Committee/Health Services Division	July 21, 2021
	Medical Policy Committee/Health Services Division	June 15, 2022
	Medical Policy Committee/Health Services Division	July 19, 2023

Published: 09/01/2023

Effective: 09/01/2023