

Type 2 Diabetes Trial for Recently Diagnosed Patients (Tirzepatide Versus Intensified Conventional Care)

Protocol	I8H-MC-GPHE
Ideal Patient Profile	Adult (18+), recently diagnosed w/ T2DB in the past 4 years, currently on stable dose (≥ 90 days prior to visit 1) of metformin (≥ 1500 mg/day OR maximum tolerable dose), A1C between 7% – 9.5%, with no prior history of insulin OR injectable GLP-1 usage
Study Duration	4 Years
Visit Schedule	Monthly for 6 months, then quarterly thereafter
Reimbursement	\$3125
Key Inclusions:	
Age	≥ 18 Years
Indication	T2DM (newly diagnosed in past 4 years)
A1C	7% - 9.5%
BMI	≥ 25 kg/m ² to ≤ 45 kg/m ²
Con Med (required)	Metformin (stable dose for at least 90 days prior to visit 1) ≥ 1500 mg/day or maximum tolerated dose
Key Exclusions:	
Medical Conditions	<ul style="list-style-type: none"> • T1DB • Evidence of active autoimmune abnormality (e.g., Lupus) likely to require treatment with systemic glucocorticoids in the next 2 years • History of diabetic retinopathy or diabetic macular edema • Any hemoglobin abnormality that might interfere with HBA1C measurement
Con Med (exclusionary)	<ul style="list-style-type: none"> • Any prior use of insulin <i>except</i> for gestational diabetes or emergency use not to exceed 14 days of treatment (post-treatment washout required) • Any prior use of injectable GLP-1 RAs (Rybelsus is acceptable with 90-day washout) • Treated with prescription or OTC drugs that promote weight loss within 90 days of visit 1 (washout required) • Receiving systemic glucocorticoid therapy within 1 month prior to visit 1 or between visit 1 and visit 3 (washout required)
Ketoacidosis or Hyperosmolar State	History of condition prior to screening
Hypoglycemia	Any severe event or incidence of hypoglycemic unawareness within 6 months to visit 1
CKD	eGFR < 30 ml/min/1.73 m ²
Blood Transfusion	Not applicable
Heart Disease or CVD Risk	Prior to Visit 1, have... <ul style="list-style-type: none"> • MI OR Stroke or Congestive HF • Coronary, carotid or peripheral revascularization • Nontraumatic amputation
Liver Disease	Acute or chronic hepatitis is exclusionary
Pancreatitis	Exclusionary if patient has any history of acute or chronic pancreatitis
Thyroid Disease	<ul style="list-style-type: none"> • Calcitonin ≥ 35 ng/L • Evidence of uncontrolled endocrine abnormality • Family or personal history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2
Bariatric Procedures	Have had or planning to have gastric bypass, sleeve gastrectomy or restrictive bariatric surgery OR chronically taking drugs that affect GI motility OR has a history of gastric emptying abnormality (e.g., diabetic gastroparesis)
Psychiatric Disorders	Patient has a history or current significant psychiatric disorder considered clinically significant in the opinion of the investigator that may preclude the patient from completing the protocol
Cancer	Malignant neoplasms within past 5 years prior to screening with exceptions for basal or squamous skin cancer, stage 0 non-invasive cervical or prostate cancer