

Guidance for Semaglutide 2mg (OZEMPIC) Injection July 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

Semaglutide 2mg (OZEMPIC) is now available in an 8mg/3mL prefilled pen.¹ This guidance is not intended to replace the National criteria for use.

The FDA approval was based on the 40-week SUSTAIN FORTE trial comparing semaglutide 2mg to semaglutide 1mg as add-on to metformin +/- sulfonylureas in 961 patients with type 2 diabetes.²

Patient demographics include mean age 58 years, 59% men, 88% white, mean duration of diabetes 9.5 years, mean A1C 8.9%, mean fasting plasma glucose 194mg/dL, mean weight 99.3kg, and 53% on sulfonylureas.

The primary outcome was change from baseline at week 40 in A1C. The estimated treatment difference between 2mg and 1mg was 0.2%. Changes in select glycemic outcomes and weight are shown in the table.

	Semaglutide 2mg	Semaglutide 1mg	ETD [95%CI]
Change in A1C (%)			
▪ All pts	-2.1	-1.9	-0.2 [-0.31 to -0.04]
▪ Metformin only	-2.3	-2.1	-0.2 [-0.4 to -0.04]
▪ Metformin + SU	-2.0	-1.8	-0.2 [-0.41 to -0.06]
A1C <7% (%pts)	64	56	-
FPG (mg/dL)	-59	-55	-
Change in BW (kg)			
▪ All pts	-6.4	-5.6	-0.77 [-1.55 to 0.01]
▪ Metformin only	-7.7	-6.6	-1.15 [-2.24 to -0.06]
▪ Metformin + SU	-6.2	-5.5	-0.72 [-1.7 to 0.31]‡
% weight loss	7.2	6.2	-0.98% [-1.75 to -0.2]

BW=body weight; ETD=estimated treatment difference; FPG=fasting plasma glucose; SU=sulfonylurea

‡Not statistically significant

Mean changes in blood pressure from baseline at week 40 were -5.3 mmHg systolic and -0.8 mmHg diastolic with semaglutide 2.0 mg and -4.5 mmHg systolic and -0.4 mmHg diastolic with semaglutide 1.0 mg.

Adverse events including gastrointestinal (nausea, vomiting, diarrhea) and hypoglycemia were comparable. Other adverse events of interest (diabetic retinopathy complications, hepatobiliary, acute gallstone disease, pancreatitis, cardiovascular disease, allergic reactions) were not increased with the 2mg dose compared to the 1mg dose.

Suggestions when considering semaglutide 2mg as an intensification option for patients with type 2 diabetes treated with semaglutide 1mg in need of additional glycemic control

1. Verify adherence to current therapy
2. Optimize current non GLP1 agonist anti-glycemic medications as appropriate
3. Consider addition of empagliflozin or insulin if appropriate

¹Semaglutide (OZEMPIC) is available on VANF, with doses up to 1 mg on National Contract (2mg dose is not on National Contract)

²Frias JP, et al. [Efficacy and safety of once-weekly semaglutide 2.0 mg versus 1.0 mg in patients with type 2 diabetes \(SUSTAIN FORTE\): a double-blind, randomized, phase 3B trial.](#) Lancet Diabetes Endocrinol. 2021 Sep;9(9):563-574.