

# CURRENT FDA-APPROVED MONO & DUAL AGONISTS\*1-3,9

CLASS	GENERIC NAME	BRAND NAME	FDA APPROVAL INDICATION (as of August 2023)*	KEY STUDY SERIES NAME(S)+	DOSE RANGE/FREQUENCY	DEVICE DESCRIPTION
Mono GLP-1 agonists (expected A1c lowering: 0.5% to 1.6%)	exenatide (immediate release)	Byetta (injectable)	10 years old and older, type 2 diabetes, adjunct to diet and exercise#, glycemic control	EXSCEL	5 or 10 mcg twice/day, take within 60 min before eating	Pen (requires pen needles prescription)
	exenatide XR	Bydureon (injectable)	10 years old and older, type 2 diabetes, adjunct to diet and exercise#, glycemic control	DURATION	2 mg weekly	Pen injector-Bydureon BCise
	liraglutide	Victoza (injectable)	10 years old and older, type 2 diabetes, adjunct to diet and exercise#, glycemic control, reduces risk of major adverse cardiovascular events and established CVD	LEADER	0.6, 1.2, or 1.8 mg daily (doesn't have to be taken before meals)	Pen (requires pen needles prescription)
	liraglutide	Saxenda (injectable)	Adults: BMI > 30 or > 27 if weight-related medical issues  Pediatric: 12 years old and older, initial weight > 60 kg (132 lbs)	SCALE	3 mg maximum dose daily	Pen (requires pen needles prescription)
	dulaglutide	Trulicity (injectable)	Adults, type 2 diabetes, adjunct to diet and exercise#, glycemic control, reduces risk of major adverse cardiovascular events and established CVD, or multiple risk factors	REWIND	0.75, 1.5, 3, or 4.5 mg weekly	Pen injector
	semaglutide	Ozempic (injectable)	Adults, type 2 diabetes, adjunct to diet and exercise#, glycemic control, reduces risk of major adverse cardiovascular events and established CVD	SUSTAIN, SELECT	0.25, 0.5, 1, or 2 mg weekly	Pen (comes with needles)
	semaglutide	Rybelsus (oral)	Adults, type 2 diabetes, adjunct to diet and exercise#, glycemic control	PIONEER	3, 7, or 14 mg daily in the morning. Take on empty stomach alone with 4 oz water, at least 30 minutes before eating and drinking	N/A (an oral medication)
Dual GLP-1 agonist/ GIP (expected A1c lowering: 1.8% to 2.4%)	semaglutide	Wegovy (injectable)	Adults: BMI > 30 or > 27 if weight-related medical issues.  Pediatric: 12 years old and older, initial BMI 95 <sup>th</sup> percentile, age, sex	STEP	2.4 mg maximum dose	Pen (comes with hidden needle on the pen)
	tirzepatide	Mounjaro (injectable)	Type 2 diabetes	SURPASS, SURMOUNT	2.5, 5, 7.5, 10, 12.5, or 15 mg daily	Pen injector

\*LISTED CHRONOLOGICALLY AS THEY WERE APPROVED BY THE FDA.

\*Details on FDA approval indication(s) as of August 2023. With filed research outcomes, the FDA can approve additional indications that are then integrated into the package insert. The FDA can issue new label warnings for FDA-approved medications at any time. In late September 2023, the FDA added a warning on the label of semaglutide (Ozempic), telling users of the potential for an increased risk of ileus (an intestinal blockage). The FDA already required such a warning label for Mounjaro and Wegovy. Reference: Drug safety-related labeling changes (SRLC). FDA website. <https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/index.cfm?event=searchdetail.page&DrugNameID=2183>. Updated September 22, 2023. Accessed October 4, 2023.

#The term "diet and exercise" has been used by the FDA for medication approvals for decades.

+These acronyms for studies represent some, but not all, of the series of studies conducted in the research and development for each medication to support FDA approval and use indications and approval by other global medication institutions.