

#### **DISEASE BURDEN**



Both the prevalence and incidence of T2DM and obesity are increasing throughout the world, with the rising prevalence of both conditions being the steepest among LMICs. High fasting plasma glucose and high BMI are part of the top three risk variables for years of life lost in 2040, underscoring the global health challenge posed by these conditions.



### CLINICAL RELEVANCE

Tirzepatide, a once weekly sub-cutaneous dual GLP-1 / GIP receptor agonist, is highly effective in achieving and maintain glycaemic targets in people with T2DM and promoting weight loss in adults with obesity or overweight. It has also been approved for the reduction of the severity of sleep-apnea in adults with obesity. Successful clinical trials demonstrated benefits in adults with obesity and heart failure with preserved ejection fraction, with an application for approval submitted in 2024.



### SERVICE DELIVERY ENABLERS

Point-of-care testing for the detection, diagnosis, and monitoring of blood glucose is available in almost 90% of primary healthcare facilities in LMICs and almost 50% of LICs. GLP1-RA are not yet included in national guidelines or clinical protocols in LMICs, hence companion treatments might vary. However, the availability and affordability of metformin, the widely recognized first-line therapy, is generally good in LMICs. Second-line treatments remain inconsistently available, with sulfonylureas more common in middle-income (53%) than low-income countries (11%), while access to SGLT2i (16-20%) and DPP4i (25-27%) is similarly limited, with minimal government provision.



## MANUFACTURING

The API is manufactured by chemical route, which might be complex. All excipients are commonly used in injectable formulations. Manufacturing process is simple, however aseptic processing will be required. Finished product is provided in an autoinjector, which is considered a device. Shelf life is 2 years under refrigeration.





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# INTELLECTUAL PROPERTY LANDSCAPE

The primary patent on tirzepatide has been granted so far in at leas 37 LMICs, including India, and pending in another 14 with an expected expiry in 2036. Secondary patents on the subcutaneou formulation have been filed and granted widely in LMICs and are expected to expire in 2039.

### **REGULATORY**

Product is approved with USFDA and EMA. Since Tirzepatide is a small peptide, potential licensees can follow typical ANDA pathway (para III) like in the case of a small molecule, or EU-M4all or Swissmedic MAGHP pathway. No clinical studies will be required. Biowaiver is possible based on qualitative and quantitative similarity.

### MARKET



Tirzepatide is primarily available in high income countries with a limited presence in low-income countries (such as India and Bangladesh). There is currently no public information on the access plans.