2. The Financial Case for Implementing Stage 2 and Early Stage 3 T1D Treatment in a Hospital-Based Endocrinology Program

Summary:

Early-stage T1D care with screening, staging, monitoring, and treatment with teplizumab offer both clinical and financial value. Health systems that implement structured pathways for Stage 2 and early Stage 3 T1D reduce the risk of DKA, improve outcomes, and systematize predictable clinical throughput. The major determinant of positive margin is drug acquisition cost (340B or strong commercial payer mix). When infusion centers maintain high-capacity utilization, early therapy pathways can generate net-positive contribution margins through infusion services, onboarding diabetes technology, and longitudinal follow-up. Evidence from microsimulation models suggests that teplizumab's cost-effectiveness is sensitive to drug price and patient selection, making program design essential. A combined early-stage program strengthens population health value and reduces high-cost acute care episodes.

Context:

T1D is an autoimmune disease estimated to affect 8.75 million people worldwide[1]. Its burden is expected to increase in the coming years to 13.5-17.4 million people living with the disease by 2040[1]. A diagnosis of T1D reduces life expectancy by up to 12 years[2].

Approved by the US FDA in 2022 for people ≥ 8 years of age with Stage 2 T1D, teplizumab is the first DMT that can alter the course of an autoimmune endocrine disease[4]. Compared with placebo, teplizumab delayed the onset (Stage 3) of T1D by ~2.7 years[4] . The clinical availability of teplizumab is a significant development[6,7] and has intensified discussions amongst health systems to evaluate the financial and operational impact of implementing a streamlined pathway for Stage 2 and early Stage 3 T1D.

Early detection and treatment can delay progression[4-8], reduce DKA[9-12], improve long-term outcomes[13], and in certain payer mixes, create a sustainable positive margin.

Why Early-Stage Programs Matter:

The financial burden of T1D translates to nearly $500,000 per person over the course of a lifetime[13]. Early clinical intervention provides clear benefit to both patients and health systems by delaying disease progression, reducing lifetime complications, decreasing DKA, and improving outcomes for patients at risk[3-13]. Many endocrinology centers have the key components of established screening and DMT programs for presymptomatic T1D:

- Outpatient endocrinology clinic infrastructure
- Autoantibody testing (through research and/or clinical laboratories)
- Diabetes education services
- Capabilities for CGM onboarding and monitoring
- Access to an infusion center capable of administering teplizumab or other DMT
- After-hours clinical support pathways to address infusion-related adverse events and other potential complications, ensuring timely assessment and escalation of care when needed

Financial Model Cost Estimates:

Cost or Operational Component	Estimated Range or Description
Drug acquisition cost	
Teplizumab wholesale acquisition cost (WAC)	Approximately $193,900
340B acquisition cost	Approximately $100,000–$150,000 or higher
Key financial determinant	Program financial viability is strongly influenced by access to 340B pricing or a favorable commercial payer mix
Infusion-related costs (administration only)	
Home infusion	Approximately $6,000–$8,000 or higher
Hospital outpatient infusion	Approximately $12,000–$30,000 or higher
Diagnostic staging	Approximately $700–$1,200 or higher
Ongoing monitoring	Approximately $500 or higher
Expected financial margin	
Predominantly commercial payer mix	Generally positive

Medicaid-heavy payer mix	Potentially negative, depending on drug acquisition cost, reimbursement, and patient selection
Operational considerations	Sustainable infusion capacity depends on predictable infusion volume to support efficient staffing and resource allocation

Return on investment is driven primarily by drug acquisition cost, payer mix, and patient selection, with these factors exerting a substantially greater influence on financial performance than variation in ancillary clinical costs. Infusion capacity represents a key operational constraint; maintaining cost efficiency requires sufficient and predictable infusion volume to support staffing and resource utilization. All cost estimates presented are illustrative and may vary across institutions depending on local contracting arrangements, reimbursement structures, and regional payment policies.

Financial Impact Example:

The Financial Case for Implementing Stage 2 and Early Stage 3 T1D Treatment.

Table. Key Components of an Early-Stage Type 1 Diabetes Treatment Program

Program Component	Description
EHR-based screening alerts	Automated identification of at-risk individuals using autoantibody testing based on family history, genetic risk, or early dysglycemia
Standardized care pathway	Unified approach to early-stage evaluation, staging, and management
Expedited staging and infusion access	Streamlined processes to reduce time from diagnosis to initiation of disease-modifying therapy
Home glucose monitoring	Access to intermittent or continuous glucose monitoring for early metabolic assessment
Insurance authorization support	Dedicated personnel with expertise in securing coverage for disease-modifying therapies

Infusion center coordination	Integrated scheduling to optimize efficiency and minimize treatment delays

Revenue / Cost Area	Stage 2 Contribution	Early Stage 3 Contribution	Combined Effect
Autoantibody testing & staging labs	Steady, reimbursable	Performed at diagnosis; fully reimbursable	Predictable lab revenue stream
Clinic visits (new + follow-up)	Follow-up during staging/treatment	Intensive follow-up during first 4–6 weeks	Higher clinical throughput with existing staff
Infusion center services (teplizumab)	Strong positive margin for biologic infusion	Same infusion protocol	Consistent utilization of infusion chairs
Diabetes education / CGM onboarding	Usually optional or delayed	High uptake	Expands billable education services
Avoided DKA & acute admissions	Lower long-term risk	Avoids immediate high-cost admissions	Cost avoidance for systems under value-based contracts
Long-term retention	High likelihood of continuity of care	Nearly universal follow-up for early Stage 3	Stable longitudinal revenue from comprehensive diabetes program

Results:

After 12 months (Illustrative):

- Eight Stage 2 patients received teplizumab.
- 16 early Stage 3 patients completed rapid diagnosis-to-treatment care, including insulin initiation and education within two weeks.
- Utilization of existing infusion-center capacity improved by 12%.
- The combined early-stage program generated a net-positive contribution margin, due largely to infusion services + ongoing follow-up care.

- With fewer patients arriving in DKA, the system avoided an emergency and inpatient cost burden (varies by region and payer).
- Combining infusion therapy with early education and technology adoption drives predictable, integrated revenue streams.
- The model strengthens system value propositions for population health and prevents high-cost acute care episodes.

This integrated model aligns with population health goals by reducing emergency department utilization, lowering hospital admissions for DKA (a high-cost, high-variability event), and improving continuity of care. Systems operating under value-based or shared-risk contracts benefit significantly from predictable reductions in acute episodes.

Costs and cost-effectiveness articles (2 microsimulation model articles):

What it reports (cost / ROI / cost-effectiveness)
A full microsimulation model. If teplizumab is priced under US $48,900, then treating *all at-risk individuals* becomes cost-effective (under common willingness-to-pay thresholds). If the cost of therapy is > $100,000, treating only 25% of patients at risk will be cost-effective. If current annual cost of management of T1D patients and cost of teplizumab therapy is considered, it may be cost-effective only if the prospective patient fulfills all the favorable criteria of therapeutic response- HLA-DR3 negative, HLA-DR4 positive and negative anti ZnT8 antibody status[16]-
Using microsimulation modeling, they examined the cost-effectiveness of six alternative prevention-treatment strategies defined by a combination of three preventive immune therapies (teplizumab, ATG, or no therapy) and two insulin management strategies (AID or conventional insulin management). Effectiveness was measured by quality-adjusted life years (QALYs). Among the six strategies considered, preventive ATG therapy followed by AID was the most cost-effective. It entailed $394,250 in lifetime costs and yielded 19.13 QALYs. These costs were lower and QALY gains higher than those with strategies that did not involve immune therapy or AID. Preventive teplizumab therapy followed by AID generated 0.25 more QALYs than ATG therapy followed by AID, albeit at an additional cost of $153,670, resulting in an incremental cost-effectiveness ratio of $369,890/QALY. 17
Notes that a 14-day course of teplizumab costs ~**US $193,000**. The article frames cost as a major limiting factor for broader use, highlighting the need for careful patient selection to optimize value.[14]
Provides a real-world cost benchmark: each vial costs ~$13,850; full 14-day course totals about **$193,900**. Useful for pricing-based ROI modeling.[15]

In conclusion, early-stage T1D programs deliver measurable clinical and financial value when supported by strong operational alignment, predictable infusion capacity, and favorable payer structures. Strategic program design, particularly around 340B access, patient selection, and infusion workflow—remains the key determinant of sustainable ROI. As health systems increasingly shift toward value-based care, early detection and disease-modifying therapies represent a high-yield opportunity to reduce acute-care burden and enhance population health outcomes.