EE119

Cost-Effectiveness and Potential Value of T-Regulatory Cell Therapy in the Treatment of Moderate-to-Severe Crohn's Disease

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BACKGROUND

Crohn's disease (CD) is a chronic autoimmune inflammatory condition causing abdominal pain, diarrhea, and GI bleeding; if undertreated, it leads to bowel damage, fistulas, and surgery.

CD affects ~1 million Americans; annual healthcare costs exceed $3.48 billion (Ganz 2016).

Biologics — infliximab (IFX, anti-TNF) and ustekinumab (UST, anti-IL-12/23) — are first-line treatment for moderate-to-severe CD but are not curative and efficacy wanes over time.

T-regulatory (Treg) cell therapy is an emerging modality targeting immune tolerance, evaluated in organ transplant rejection, GVHD, and type 1 diabetes. Allogeneic (off-the-shelf) approaches offer potential scalability.

No clinical efficacy data exist for Treg therapy in CD. This analysis uses a threshold framework to determine conditions under which Treg therapy would be cost-effective.

OBJECTIVES

1. Estimate the cost-effectiveness of allogeneic Treg therapy vs. IFX and UST in biologic-naïve moderate-to-severe CD.

2. Determine the economically justifiable price (EJP) at WTP $150,000/QALY.

3. Test sensitivity to Treg efficacy advantage and price.

METHODS

Model: Hybrid decision tree (8-wk induction) + Markov model (39 × 8-wk cycles = 6.15 years). Microsoft Excel 2024.

Population: Age 35, 71 kg, 50% male, moderate-to-severe CD, biologic-naïve (Aliyev 2019).

Health States: Mod-Severe · Mod-Severe Responder · Mild · Remission · Surgery · Death

Comparators: Ustekinumab (UST) · Infliximab (IFX) · Treg therapy (hypothetical allogeneic)

Treg Efficacy: Base case: 20% reduction in probability of mod-severe or surgery vs. UST. Sensitivity Analysis: 10–30%.

Treg Price: Manufacturing $4,979/dose; retail $19,917/dose; 2 doses = $39,834 base case. Sensitivity Analysis: ±50%.

Transitions: Induction: Aliyev 2019 Supp. Table 3. Maintenance: Holko et al. 8-week cycles.

Utilities: Remission 0.82 · Mild 0.73 · MSR 0.65 · Mod/Sev 0.57 · Surgery 0.57 (Aliyev 2019; Buxton 2007)

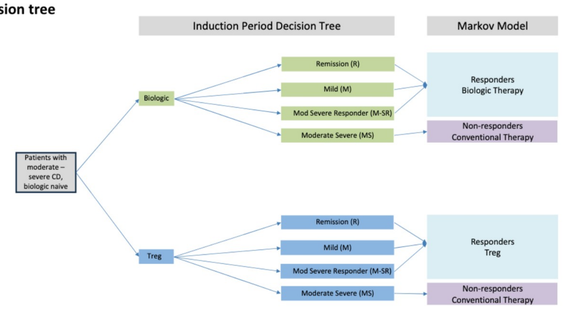
Drug Costs: CMS ASP April 2025. Admin: CMS Physician Fee Schedule. All costs in 2025 USD.

Perspective: Formal U.S. healthcare sector. Discount rate: 3%/year.

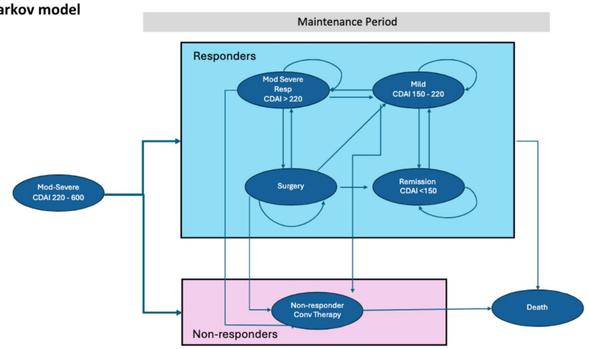
Analyses: Base-case ICER; NMB at WTP $150K; EJP; One-way Sensitivity Analysis (9 parameters); PSA (n = 1,000).

MODEL STRUCTURE

Decision tree



Markov model



KEY MODEL INPUTS

Parameter	Base-Case Value	Source
Time horizon	**6.15 years (39 cycles)**	Aliyev 2019
Cycle length	**8 weeks**	Model assumption
Discount rate	**3%/year**	Standard
Treg efficacy advantage	**20% vs. UST (base)**	Model assumption
Treg price (base)	**$39,834 (2 doses)**	ten Ham 2020; Hall 2021
Utility: Remission	**0.82**	Aliyev 2019; Buxton 2007
Utility: Mild	**0.73**	Aliyev 2019; Buxton 2007
Utility: Mod-Sev Responder	**0.65**	Aliyev 2019; Buxton 2007
Utility: Moderate-Severe	**0.57**	Aliyev 2019; Buxton 2007
Utility: Surgery	**0.57**	Aliyev 2019; Buxton 2007
UST induction cost	**$4,995 (390 mg IV)**	CMS ASP Apr 2025 (J3358)
IFX induction cost	**$3,666 (3×350 mg IV)**	CMS ASP Apr 2025 (J1745)
WTP threshold (primary)	**$150,000/QALY**	Analysis assumption

Sources: Aliyev 2019; Buxton 2007; ten Ham 2020; Hall 2021; CMS ASP/Physician Fee Schedule April 2025

$65,917 *ICER: Treg vs. IFX ($/QALY)*

4.07 *Treg QALYs (6.15-year horizon)*

$529,388 *Treg NMB at WTP $150K*

$95,382 *Economically Justifiable Price*

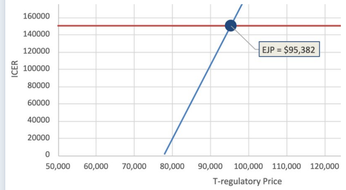
BASE-CASE RESULTS

Strategy	QALYs	Cost ($)	ICER vs. UST	ICER vs. IFX
UST	3.90	$118,672	–	Dominated
IFX	3.95	$73,124	Dominant	–
Treg ($39,834)	4.07	$80,855	**Dominant**	**$65,917/QALY**

Net Monetary Benefit @ WTP $150,000/QALY

IFX	$519,526
Treg	**$529,388 ← Highest**
UST	$466,925

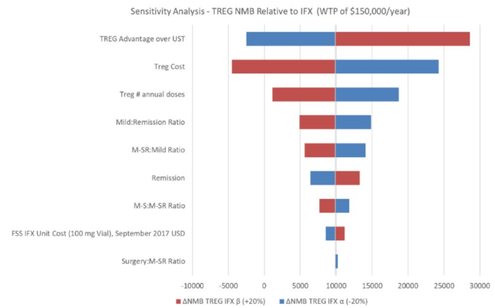
ECONOMICALLY JUSTIFIABLE PRICE

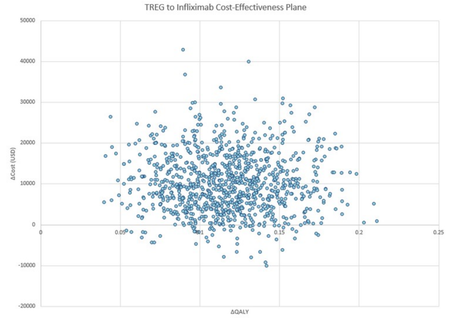


At WTP $150,000/QALY:
EJP = $95,382

Base-case price ($39,834) is well within the EJP, indicative of substantial pricing headroom.

SENSITIVITY ANALYSIS: UNIVARIATE & PROBABILISTIC





SCENARIO ANALYSES

Scenario	Treg NMB	IFX NMB
10% efficacy advantage	$516,623	$519,527
20% efficacy (base case)	**$529,388**	$519,527
30% efficacy advantage	$548,121	$519,527
Price +50% ($29,957/dose)	$515,005	$519,527
Price −50% ($9,986/dose)	$543,773	$519,527

DISCUSSION

Treg therapy yielded the highest NMB ($529,388) and QALYs (4.07) at WTP $150,000/QALY, indicating it is the most cost-effective strategy under base-case assumptions.

The ICER of $65,917/QALY versus IFX falls well below the $100,000–$150,000/QALY WTP thresholds used in U.S. HTA, consistent with cost-effectiveness.

IFX dominated UST in the base case, consistent with prior analyses (Aliyev 2019). Treg's extended dominance over both reflects its superior QALY generation.

The EJP of $95,382 substantially exceeds the base-case price of $39,834, providing meaningful pricing headroom without compromising cost-effectiveness.

The Sensitivity & Scenario Analyses identified Treg efficacy advantage and price as the dominant drivers of uncertainty.

PSA demonstrated most iterations in the NE quadrant (more effective, more costly than IFX), consistent with a therapy whose value depends on the WTP threshold applied.

CONCLUSIONS

Allogeneic Treg therapy is cost-effective for moderate-to-severe CD under an assumed ≥20% efficacy advantage vs. UST at a price of ~$39,834 (WTP $150,000/QALY).

The EJP of $95,382 provides actionable pricing guidance for translational development and early HTA planning.

Further investigation is needed as clinical trial data emerge to validate these projections.

LIMITATIONS

No Treg Late Stage Clinical Trial data available. Efficacy assumptions tested in Sensitivity Analysis but not clinically validated.
6.15-year horizon may understate long-term benefit if Treg disease modification is durable.
Formal U.S. healthcare perspective; excludes indirect costs (lost productivity).
Conventional therapy arm simplified; step-up therapy sequencing not modeled.

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