

Why We Need to Keep Costs Down for Cell Therapies

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POLL

What is the median U.S. family income?

- \$48,000
- \$58,000
- \$68,000
- \$78,000
- \$88,000

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Premiums for average family health insurance plans make up what percent of the median family income?

- 5%
- 10%
- 15%
- 25%
- 35%

Affordability of Health Insurance

Median family income-- 2019	\$88,149
Average family health insurance premium—2019	\$20,576
Average worker contribution for family health insurance	\$6,015
Percentage of income that goes to health insurance premiums	23.3%
Percentage of income for worker's contribution	7.0%

Rectifying Unduly High Prices For Therapies

- Drugs are a large contributing factor to high premiums, considering they account for **17%** of national health care expenditures. Over **20%** of health care premiums.
- For cell therapies, there are at least two steps we can take to rectify high prices:
 - Determine fair pricing for cell therapies
 - Reduce prices for marginally effective therapies and those approved through accelerated approval

Fair Pricing

New CAR-T therapy from Bristol, Bluebird effective but too costly, ICER finds



ICER Review

- Abecma list price: \$419,500 for one treatment
- ITT was 63% and median progression free survival 8.6 months.
- OS was 19.4 months compared to 9.9 months.
- 1.25 year QALY improvement
- 51% grade 2+ cytokine release syndrome
- Cost-effective ratio: \$319,000 per QALY gained

ICER Review

- ICER recommendation:

Price cut of over 50% to bring down to \$100,000 per QALY threshold

\$100,000 per QALY	\$150,000 per QALY
\$192,000	\$245,000

Table 4.8. QALY-Based Threshold Analysis Results

	WAC per Unit	Net Price per Unit	Unit Price to Achieve \$50,000 per QALY	Unit Price to Achieve \$100,000 per QALY	Unit Price to Achieve \$150,000 per QALY	Unit Price to Achieve \$200,000 per QALY
Ide-Cel	\$419,500	N/A	\$140,000	\$192,000	\$245,000	\$295,000
Cilta-cel (preliminary)*	N/A	N/A	\$208,000	\$317,000	\$427,000	\$537,000
Belantamab	\$8,277		\$7,300	\$8,300	\$9,300	\$10,400

N/A: not available, evLYG: equal-value life years gained, QALY: quality-adjusted life years gained, WAC: wholesale acquisition cost.

*Using placeholder price for cilta-cel

When Is a Drug Price Unfair

- CAR-T cannot be expensive just to be expensive. The price must reflect value to patients and society.
 - Current multiple myeloma cell therapy is not there yet
- If this therapy is given to all ~150,000 Americans with MM, this therapy would cost \$63 billion.
- For 0.05% of the population we would pay more than 10% of all drug spending or 0.33% of GDP.

Complete Life Principle

- Benefits and costs should be considered over a whole life, not just a narrow time frame
- “What is the cumulative lifetime cost of a drug or therapy?” vs “What is the cost per dose or annual cost?”

Limited Resources Principle

- The just price of a drug should reserve enough resources for people to pursue valuable life activities
- Resources are scarce: fair drug prices must have it so people can still allocate resources to diverse interests

Value Principle

- There should be a relationship between price and benefits.
- A drug or therapy that generates a more improvement in meaningful outcomes—longevity or quality of life—should command a higher price.

Lifetime Earnings Standard for Affordability

- An average white man with a bachelor's degree life-time earnings is \$2.27 million.

Raising a Child	\$233,000
Food	\$243,000
Housing	\$770,000
Transportation	\$304,000
Public College	\$80,000
OTHER	\$640,000

Price of Cell Therapies

- An average person has \$640,000 for everything else: internet, cell phones, books, alcohol, entertainment, health care, clothing, childcare, vacations, etc.
- Is it ethical to charge \$419,000 for one cellular therapy —which occurs after much spending on multiple other treatments?

Remedying Accelerated Approval

High Costs, For What Results?

- Since 1992 the FDA has permitted early approval to drugs based off of “surrogate endpoints”
- Supposed to have subsequent confirmatory studies showing clinically meaningful outcomes of improved survival or quality of life
- Of drugs approved through the accelerated pathway fully 28% had never completed confirmatory trials

Changes Needed for Accelerated Approval

- Only pay full price for drugs that are proven to work on outcomes patients care about: overall survival and improved quality of life
 - Until drugs complete confirmatory trials, they should be paid at a price 80% of existing standard of care.
- Create a deadline for drugs to complete confirmatory trials after the accelerated approval date (e.g. 3 years)

Money

- The average cost of a new cancer drug is roughly \$10,000 per month.
- Drugs must prove their effectiveness **before** demanding high prices
- Saving the system money by not spending on drugs that have not been proven effective for important endpoints (e.g. survival)

Conclusion

- We need to have more reasonable cancer drug costs
- We cannot have high costs just because other drugs have high costs
- Costs need to be related to health benefits and other things people need to spend money to live a normal life