Review of Cell Therapy Access Landscape

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OBJECTIVES

Cell therapies represent a growing treatment class for severe diseases, though high prices raise concerns regarding payer budget impact and how it may affect patient access. This research aims to evaluate current trends in the pricing and commercial payer coverage of FDA-approved cell therapies in the United States.

METHODS

A comprehensive review of publicly available financial reports, press releases, and commercial payer coverage policies was used to assess pricing and access trends for cell therapies that were FDA-approved as of January 2025. The analysis excluded hematopoietic progenitor cell transplantation, cellularized scaffold products, and cell-based gene therapies. Coverage policies of ten of the largest US commercial insurers by covered lives were compared against FDA-approved indications and pivotal trial inclusion / exclusion criteria to evaluate payer management strategies.

Cell Therapies Analyzed*

Name *Launch*	Average WAC (USD)	US Revenue (FY 2024, USD in millions)	Indication *(Simplified)*
Abecma *2021*	$528k	$242	Adults with R/R multiple myeloma after 2+ lines of therapy
Amtagvi *2024*	$562k	$104	Adults with metastatic melanoma after PD-1 blocker
Aucatzyl *2024*	$525k	Not available	Adults with R/R precursor B-cell ALL
Breyanzi *2021 2024 2024 2024*	$531k	$591	Adults with LBCL who are refractory to 1L chemotherapy or R/R to 2+ lines of therapy
			Adults with R/R CLL or SLL after 2+ prior lines of therapy
			Adults with R/R FL after 2+ prior lines of therapy
			Adults with R/R MCL after 2+ prior lines of therapy
Carvykti *2022*	$555k	$963	Adults with R/R multiple myeloma
Kymriah *2017 2018 2022*	$582k	$443**	≤25 y/o patients with B-cell precursor ALL that is refractory or in 2+ relapse
	$457		Adults with R/R LBCL after 2+ prior lines of therapy
			Adults with r/R FL after 2+ prior lines of therapy
Lantidra *2023*	$300k	Not available	Adults with T1D unable to approach target HbA1c despite diabetes management/education
Provenge *2010*	$188k	Not available	Asymptomatic/minimally symptomatic metastatic hormone-refractory prostate cancer
Rethymic *2021*	$2,811k	Not available	Pediatric patients with congenital athymia
Ryoncil *2024*	$1,552k	Not available	Pediatric steroid-refractory acute GvHD
Tecartus *2020 2021*	$462k	$234	Adults with R/R MCL
			Adults with R/R B-cell precursor ALL
Tecelra *2024*	$727k	$1.2	Adults with metastatic synovial sarcoma
Yescarta *2017 2021*	$504k	$662	Adults with LBCL who are refractory to 1L chemotherapy or R/R to 2+ lines of therapy
			Adults with R/R FL after 2+ prior lines of therapy

Table 1. Summary of cell therapies included in this analysis, cost calculated as of Apr. 2025
**Non-exhaustive; **World revenue as US not available; †Approved for 1-3 doses; Cost calculated as of Apr. 2025*
ALL: Acute lymphoblastic leukemia, CLL: Chronic lymphocytic leukemia, FL: Follicular lymphoma, GvHD: Graft versus host disease, LBCL: Large B-cell lymphoma, MCL: Mantle cell lymphoma, PA: Prior authorization, R/R: Relapsed/refractory, SLL: Small lymphocytic lymphoma, T1D: Type 1 diabetes, WAC: Wholesale acquisition cost

RESULTS

Although cell therapies are generally priced around $500K (driven mostly by the plethora of similarly priced CAR-T therapies), coverage is rather favorable. Most policies align with pivotal trial inclusion / exclusion criteria to ensure use within the studied population, while many others reflect the therapies' indication statements, which often specify relapsed / refractory disease and required prior lines of treatment. CAR-T therapies approved for the same indication generally exhibit consistent pricing and coverage patterns, and those approved for multiple indications typically receive comparable coverage across their approved uses. Differences in coverage criteria for therapies within the same indication often reflect nuances in trial design and indication statement specificity. For example, Kymriah's FL indication did not include an ECOG requirement for the pivotal trial, though both Yescarta and Breyanzi did include this inclusion criterion, which was frequently included across all three therapies' policies. For other types of cell therapies with higher prices, such as Ryoncil and Rethymic, requirements are more often to / beyond trial criteria or non-coverage, likely to manage financial risk.

Definitions of Coverage Criteria

SUBHEADING	Definition
N/A	No coverage criteria found
PA to indication statement	Requirements for coverage do not extend beyond the approved indication
PA to NCCN	Requirements for coverage are determined by NCCN recommendation
PA to trial	Requirements for coverage do not extend beyond the inclusion/exclusion criteria in the pivotal trial
PA beyond trial	Requirements for coverage extend beyond the inclusion/exclusion criteria in the pivotal trial
Not covered (NC)	Medication is not covered by the payer; using the medication would mean completely out of pocket costs

Table 2. Definitions of coverage criteria used in analysis

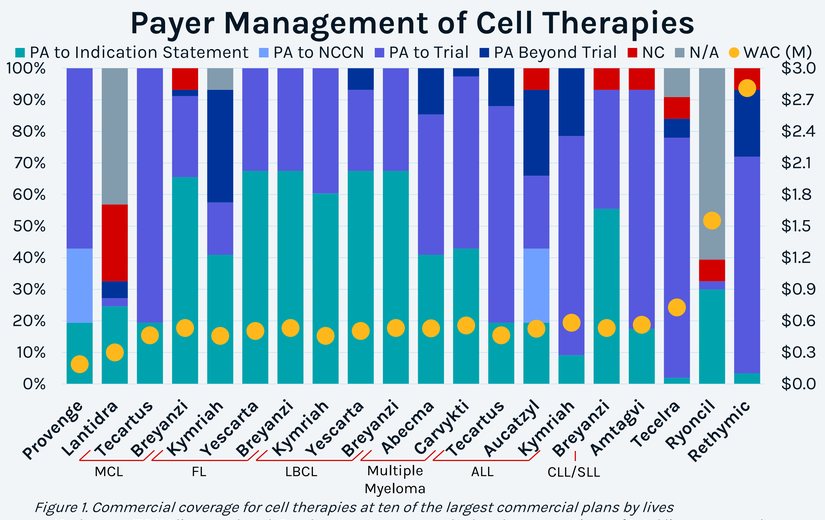

Figure 1. Commercial coverage for cell therapies at ten of the largest commercial plans by lives n=10 plans, n=172.1M lives analysed. Graph percentages are calculated as proportions of total lives managed.

About 60% of lives do not have a policy for Ryoncil (approved Dec 2024), likely due to recent approval in combination with high cost; Aucatzyl (approved Nov 2024) and Tecelra (approved Aug 2024) have considerably more available policies. Lantidra, which is approved for T1D, also has >40% of lives lacking a policy, likely due to competition with lower cost options.

CONCLUSIONS

Cell therapy access is driven primarily by time on market, as well as indication-specific dynamics such as disease prevalence, number of competitors, urgency to treat, and demonstrated efficacy / value. The hope of durable therapeutic benefit and high cost of cell therapies generally leads to moderate access restrictions, with many therapies experiencing restrictions beyond trial criteria from at least one payer. As payers become more familiar with the management of cell therapies, the process for coverage is becoming increasingly streamlined. Revenue data also suggests low correlation between payer management and uptake; instead, factors such as addressable patient population, clinician perception, prescribing behavior, site of care management, guideline recommendations, and time on market are potential key drivers of utilization.

FUTURE IMPLICATIONS

As more cell therapies come to market, patient access remains critical, particularly considering the severity of the diseases they treat - which are commonly life-threatening relapsed/refractory cancers. Despite generally lower prevalences, the high costs of cell therapies can have substantial impacts on payer budgets, so access is restricted to populations with proven efficacy and safety from the pivotal trial. Payers will likely continue to have more stringent criteria as more cell therapies are approved, particularly for higher cost (i.e., >$1M) therapies. Policies for cell therapies with indication-specific competitors may start to have preferred options and stricter policy requirements on the non-preferred products. Proactive market access and value strategy planning are critical to minimize commercialization barriers.

REFERENCES

For indication/revenue:

1. Abecma: https://www.bms.com/
2. Amtagvi: https://www.iovance.com/
3. Aucatzyl: https://www.autolus.com/
4. Breyanzi: https://www.bms.com/
5. Carvykti: https://www.jnj.com/
6. Kymriah: https://www.novartis.com/
7. Lantidra: https://www.celltransinc.com/
8. Provenge: https://www.dendreon.com/
9. Ryoncil: https://www.mesoblast.com/
10. Tecartus: https://www.kitepharma.com/
11. Tecelra: https://www.adaptimmune.com/
12. Yescarta: https://www.kitepharma.com/
13. Rethymic: https://www.sumitomo-pharma.com/

For Pricing and Covered Lives Information:

https://pricerx.medispan.com/
https://www.policytracker.com/

For cell therapy management policies:

1. UHC: https://www.uhc.com/
2. Anthem: https://www.anthem.com/
3. Aetna: https://www.aetna.com/
4. Centene: https://www.centene.com/
5. HCSC: https://www.hcsc.com/
6. Cigna: https://www.cigna.com/
7. Kaiser Permanente: https://healthy.kaiserpermanente.org/
8. BCBS MI: https://www.bcbsm.com/
9. Highmark: https://www.highmark.com/
10. Florida Blue: https://www.floridablue.com/

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