HPR85

2026 Review of Cell Therapy Access Landscape

Brooks K[1], Sy Chu M[2], Mathew J[3], Gonzalez Gil S[4]
[1]Red Nucleus, Denver, CO, USA; [2]Red Nucleus, San Francisco, CA, USA; [3]Red Nucleus, New York City, NY, USA; [4]Red Nucleus, Boston, MA, USA

1 OBJECTIVES

Cell therapies are a transforming treatment class for severe, high-burden diseases. However, high upfront costs and evolving reimbursement frameworks continue to raise concerns around payer budget impact and patient access. This research evaluates U.S. trends in pricing and commercial payer coverage of FDA-approved cell therapies through 2026.

2 METHODS

A review of U.S. Food and Drug Administration (FDA) databases, company financial disclosures, press releases, and commercial payer coverage policies was conducted to evaluate pricing and access trends for cell therapies approved in the United States. Analyses were performed for policies published on or before both January 2025 and January 2026. Hematopoietic progenitor cell transplantation, cellularized scaffold products, and cell-based gene therapies were excluded. Coverage criteria from ten major U.S. commercial insurers were evaluated against each product's indication statement and pivotal trial inclusion and exclusion (I/E) criteria to assess level of relative stringency in payer management. Wholesale Acquisition Cost (WAC) data was used to contextualize price variation across therapies. Results from the 2025 and 2026 analyses were compared to assess policy changes over time.

CELL THERAPIES ASSESSED

Name Launch Year	Average WAC (USD)	Revenue (FY 2025, USD in millions)	Indication (Simplified)
Abecma 2021	$544K	$406M	Adults with R/R multiple myeloma after 2+ lines of therapy
Amtagvi 2024	$613K	$220M (US)	Adults with metastatic melanoma after PD-1 blocker
Aucatzyl 2024	$525K	$74M (US)	Adults with R/R precursor B-cell ALL
Breyanzi 2021 2024 2024 2024	$558K	$1.4B	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	$1.5B (US)	Adults with R/R multiple myeloma
Kymriah 2017 2018 2022	$594K	$381M (US)	≤25 y/o patients with B-cell precursor ALL that is refractory or in 2+ relapse 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	$2.8M	Not Available	Pediatric patients with congenital athymia
Ryoncil 2024	$1.5M	Not Available	Pediatric steroid-refractory acute GvHD
Tecartus 2020 2021	$504K	$153M (US)	Adults with R/R MCL Adults with R/R B-cell precursor ALL
Tecelra 2024	$782K	Not Available	Adults with metastatic synovial sarcoma
Yescarta 2017 2021	$549K	$595M (US)	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

3 RESULTS

In 2026, payer access for selected cell therapies varied significantly by product and indication. Oncology CAR-Ts generally had a WAC in the mid-$500K with consistent coverage under PA to Label or Trial I/E. Within ALL, Tecartus and Aucatzyl had larger PA Beyond Trial I/E shares. From January 2025 to 2026, changes in PA criteria were modest but mostly positive, with 13 of 18 therapies seeing improved coverage and 5 worsening. Improvements mainly involved shifting lives from PA Beyond Trial I/E to PA to Label. Tecelra showed the largest increase in PA to Label coverage, reflecting its longer time on market and subsequent shifts in payer policy revisions. On the other hand, Tecartus and Breyanzi saw no coverage changes. Provenge and Rethymic experienced the biggest negative shifts, moving from PA to Label to PA to Trial or Beyond Trial. These shifts likely reflect categorization differences, formulary updates, or new policy visibility rather than true changes in payer behavior; single-plan changes should be interpreted cautiously.

COVERAGE CRITERIA DEFINITIONS

PA to Label Indication	Requirements for coverage do not extend beyond the approved indication in product label
PA to Trial I/E Criteria	Requirements for coverage do not extend beyond the inclusion/exclusion criteria in the pivotal trial
PA Beyond Trial I/E Criteria	Requirements for coverage extend beyond the inclusion/exclusion criteria in the pivotal trial
No Policy	No coverage criteria found or not covered

Table 2. Definitions of coverage criteria used in analysis

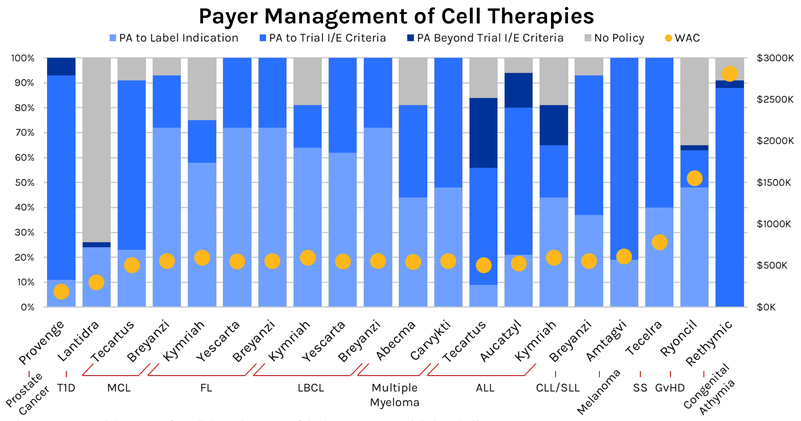

Figure 1. Commercial coverage for cell therapies at ten of the largest commercial plans by lives
n=10 plans, n=171M lives analyzed. Graph percentages are calculated as proportions of total lives managed.

	Overall Change	PA to Label Indication	PA to Trial I/E	PA Beyond Trial I/E	No Policy
Provenge	Worst	-2	1	0	1
Lantidra	Worst	0	-1	-1	2
Tecartus (MCL)	No Change	0	0	0	0
Breyanzi (MCL)	Better	2	-1	-1	0
Kymriah (FL)	Better	1	0	-2	1
Yescarta (FL)	Better	1	-1	0	0
Breyanzi (FL)	Better	1	-1	0	0
Kymriah (LBCL)	Worst	0	-1	0	1
Yescarta (LBCL)	Better	0	1	-1	0
Breyanzi (LBCL)	Better	1	-1	0	0
Abecma	Better	0	1	-2	1
Carvykti	Better	1	0	-1	0
Tecartus (ALL)	Worst	-1	1	0	0
Aucatzyl	Better	0	2	-2	0
Kymriah (ALL)	Better	2	-1	-2	1
Breyanzi (CLL)	No Change	0	0	0	0
Amtagvi	Better	0	0	1	-1
Tecelra	Better	5	-1	-2	-2
Ryoncil	Better	-1	2	1	-2
Rethymic	Worst	-1	0	1	0

Table 3. Summary of changes from 2025 to 2026. Negative number indicates that a policy changed from one categorization in 2025 to another in 2026; Positive number indicates what the category changed to in 2026

4 CONCLUSIONS

From 2025 to 2026, the access environment for cell therapies has shown minimal change. With indications concentrated in rare diseases and limited patient volumes, major payer management shifts were not seen. Similar dynamics are evident across the broader advanced therapy landscape, where access continues to hinge on differentiating from current standards of care, addressing unmet need, and maintaining evidence of long-term clinical and economic value. Payer behavior in 2026 reinforces this stability. Access for individual cell therapies varied widely by product and indication, but year-over-year movement was modest. Importantly, these changes likely reflect administrative reclassification rather than true shifts in payer intent. Single-plan movements, formulary updates, and visibility of new policies can create small shifts in management without signaling a broader trend.

5 FUTURE IMPLICATIONS

The evolving pricing dynamics and payer coverage for cell therapies may continue to create uncertainty in patient access. As pipeline expands and payer budgets tighten, payers may implement more stringent utilization management strategies to manage budget impact, including step therapy, tighter alignment to trial based inclusion criteria. In parallel, increasing financial exposure may accelerate adoption of innovative contracting, such as outcomes-based agreements, to mitigate the upfront cost burden and align payment with real world durability.
Evidence expectations may elevate as payer scrutiny grows, with greater emphasis on long-term outcomes, durability of response, and RWE generation to support coverage decisions. Manufacturers will have to proactively invest in post-launch evidence development and payer engagement strategies to demonstrate long-term clinical and economic value. As more therapies enter the market, there will be increasing competition within indications that may drive greater pressure to differentiate, which may substantially influence both pricing strategies and access positioning.

6 REFERENCES

For indication/revenue:

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

For pricing and covered lives information:

1. www.pricerx.medispan.com
2. www.policytracker.com

For cell therapy management policies:

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

Author contact details: Kevin Brooks
Email: kbrooks@rednucleus.com
www.rednucleus.com/macs