Addressing data gaps and early engagement preferences among US payers for cell and gene therapies

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Background and objective

- Since 2014, the Food and Drug Administration (FDA) has approved over 30 cell and gene therapies (CGTs) in the United States (US).[1]
- Currently, there are over 2,800 cell and gene therapies in the global development pipeline.[2]
- An unprecedented number of CGTs are in confirmatory studies and are poised to submit a Biologics License Application in the next 12 to 18 months.
- Research shows that healthcare decision-makers, such as US payers at managed care organizations, seek CGT information earlier in development than for traditional therapies to guide formulary and coverage decisions.
- Payers face significant challenges balancing the high upfront cost and financial risk of advanced therapies with the potential patient benefit and durable effect.[3]
- Cencora studied how US payers evaluate CGTs, emphasizing early engagement and identifying key areas for manufacturers to focus on during development for future payer discussions.

Methods

- An online survey was fielded through Cencora's research panel, Managed Care Network (MCN), from July 23, 2025 to August 15, 2025.
  - MCN is a proprietary research panel of over 160 healthcare executives, medical and pharmacy directors, and other experienced individuals in managed care, representing about 280 million covered lives in the US.
  - Participation in this survey was voluntary, and a modest honorarium was paid by Cencora to participants who completed the survey.
- A total of 19[a] respondents completed the survey. Respondents were from health plans and integrated delivery networks (IDNs), and all were knowledgeable about coverage and management of CGTs at their organization.
- The 19 advisors represented 154[b] million covered lives across commercial, Medicare Advantage, and Managed Medicaid books of business.

Table 1. Respondent demographics (N=19)

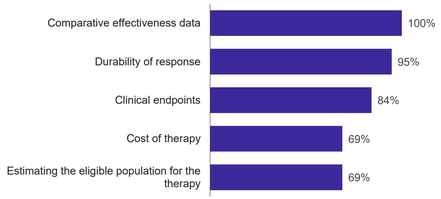
Organization type, n (%)	**Health plan**	**IDN**
	11 (58)	8 (42)
Primary role of advisors, n (%)	**Medical director**	**Pharmacy director**
	8 (42)	11 (58)
Geographic representation, n (%)	**National**	**Regional**
	3 (16)	16 (84)[c]
P&T Committee responsibilities, n (%)	**Voting member**	**Chair/co-chair**
	16 (84)	8 (42)

[a] Nineteen advisors represented 19 unique organizations.
[b] Self-reported data from payers; some lives may be double-counted.
[c] The higher percentage of regional plans was driven by respondents from IDNs, who are classified as regional plans for this study.
Key: IDN – integrated delivery network; P&T – pharmacy and therapeutics.

Results

- During early engagement with CGT manufacturers, the majority of payers valued comparative effectiveness (100%), durability of response (95%), and clinical endpoints (84%) as evidence to guide their assessments prior to FDA approval. These are specific areas that manufacturers should focus on during internal evidence planning discussions (**Figure 1**).
- Economic factors also played a significant role in early decision-making, with 69% of payers identifying cost of therapy and eligible patient population estimates as very or extremely valuable (**Figure 1**).
- The majority of payers (84%) reported gaps in the availability of both clinical data and cost/value information during early engagement with CGT manufacturers (**Figure 2**).

Figure 1. Key information payers value for CGTs during pre-approval phase



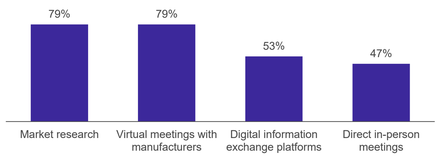
Key: CGT – cell and gene therapy; FDA – Food and Drug Administration.
Survey question: How valuable are the following types of information from manufacturers during early engagement on new CGTs prior to FDA approval? (N=19)
Note: Chart shows the top 5 responses that payers rated as very/extremely valuable.

Figure 2. Challenges payers face in engaging CGT manufacturers during pre-approval phase

Key: CGT – cell and gene therapy; FDA – Food and Drug Administration.
Survey question: What are the challenges when engaging early with CGT manufacturers prior to FDA approval? (N=19)

- Payers identified market research and virtual meetings (79%) as the most preferred methods of early engagement with manufacturers for new CGTs prior to FDA approval, followed by digital platforms for information exchange (53%). Direct in-person meetings (47%) were also valued, but to a lesser extent, underscoring the need for flexible communication channels (**Figure 3**).

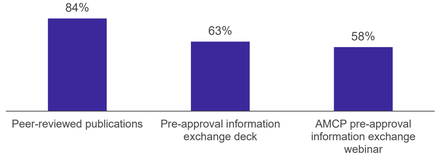
Figure 3. Payer-preferred early engagement methods for CGTs during pre-approval phase



Key: CGT – cell and gene therapy; FDA – Food and Drug Administration.
Survey question: Which methods of early engagement with manufacturers do you prefer for new CGTs prior to FDA approval? (N=19)

- Payers rated peer-reviewed publications as the most preferred pre-approval communication tool (84%), followed by pre-approval information exchange decks (63%) and Academy of Managed Care Pharmacy (AMCP) pre-approval information exchange webinars (58%). This demonstrates the necessity of multiple resource formats for payers to evaluate CGTs (**Figure 4**).

Figure 4. Payer-preferred pre-approval information exchange tools from CGT manufacturers



Key: AMCP – Academy of Managed Care Pharmacy; CGT – cell and gene therapy; FDA – Food and Drug Administration.
Survey question: Please rate the following pre-approval communication tools deployed by CGT manufacturers in terms of your preference. (N=19)
Note: Chart shows payers who rated tools as very or extremely preferred.

- Nearly 74% of payers indicated that the timeframe for coverage decisions for CGTs would be the same even if existing treatments are available, reflecting a rigorous review process regardless of unmet needs in the disease space (**Figure 5**).
  - Payers noted the average timeline to update their coverage policy for a new CGT is 4 months.

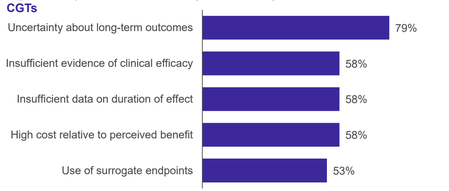
Figure 5. Payer timelines for formulary review and coverage policy updates for CGTs

Average time to update coverage policy for a new CGT: **4 months**

Key: CGT – cell and gene therapy.
Survey question: Would the timeline for your formulary reviews and coverage policy updates for CGT differ if there were no other available treatment options? (N=19)

- Most payers (74%; N=19) reported using more restrictive prior authorization criteria than the FDA label (eg, inclusion/exclusion criteria, biomarker requirements) to manage access.
- The challenges that payers face in reviewing new CGTs for coverage include uncertainty about long-term outcomes (79%), insufficient evidence of efficacy (58%), and limited data on duration of effect (58%) (**Figure 6**).

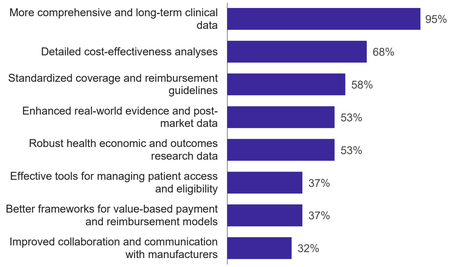
Figure 6. Payer-identified challenges in coverage determinations for new CGTs



Key: CGT – cell and gene therapy.
Survey question: What are the common challenges your organization might come across during the review of a new CGT for coverage determination? (N=19)
Note: Chart shows top 5 challenges identified by payers.

- Nearly all respondents (95%) highlighted the availability of more comprehensive and long-term clinical data as an unmet need.
  - Payers also identified additional unmet needs, such as detailed cost-effectiveness analyses (68%), and the need for standardized coverage and reimbursement guidelines (58%) (**Figure 7**).

Figure 7. Payer-identified unmet needs for new CGTs



Key: CGT – cell and gene therapy.
Survey question: What unmet needs does your organization have regarding new CGTs? (N=19)

Study limitations

- This research reflects the perspectives of managed care professionals identified from Cencora's MCN research panel; other user types (eg, healthcare providers, patients, manufacturers) were not represented in this subset.
- Since respondents voluntarily completed the MCN survey, voluntary response bias may exist, and survey results may over-represent respondents with a stronger interest in CGTs.
- Due to a small representative sample of US payers, results may not be generalizable to all payer organizations.

Conclusions

- The survey results highlight significant gaps in clinical and economic data availability during the early evaluation of CGTs by payers.
- Many of these gaps can be addressed through early planning, purposeful clinical study design, and data collection aimed at supporting a robust value narrative.
- Preferences for engagement and information-sharing channels vary, emphasizing the importance of tailored and flexible approaches for communicating with payers.
- Given the rigorous and stringent nature of coverage reviews, CGT manufacturers should prioritize addressing payer data needs in their integrated evidence generation strategies.

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