Gene and Cell Therapies: Changing Employer Plans to Optimize Patient Outcomes

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The areas we identified in our first Transformative Employer Trends column were about employers holding risk, employer plans as a dominant market payer, and employer strategies seeding market change. This column begins to identify how expensive gene and cell therapies are forcing change, and we will explore ways to expand access to these therapies transforming benefits by employer plans. Specifically, attempts to align the employer need for optimal patient outcomes with other key stakeholders in the ecosystem, and elevating the role of clinical pathways and their need to link extensive patient journeys for necessary clinical, operational, and financial aspects required for these therapies.

TRANSITION FROM "DRUG" TO "THERAPY" MANAGEMENT

It is important to clearly differentiate expensive, more durable biologics or curative therapies from traditional pharmacy benefit drugs. Employers are still learning what they are and how to manage medical benefit drugs as therapies that now include cell or gene-based therapy. While there may be traditional supportive or adjunctive drugs, the key therapies emerging from the research pipeline qualify as a drug only through the fact that it is how the US Food and Drug Administration approves them for marketing in the US.

Pathways and care guidelines have become ubiquitous in health care for decades, but plan performance to address rising care cost trends remain elusive. As a result, there is an urgent need to recognize necessary access to critical-care-journey data that is now significantly enhanced by the market entry of new therapies in recent years. The resulting enhanced care management across the entire patient journey has several key performance areas for reporting from an employer plan perspective, including integration of all data sources, patient stratification, timely patient intake, efficient and effective care coordination, patient engagement throughout the care journey, and performance measurement reporting to include effective cost management. The resulting key takeaway question is: Do we have the critical clinical and financial data to understand the impact of these new personalized medicine therapies over time?

Employer plans and their third-party administrative organizations have been incrementally transforming their efforts in recent years. That pace of change has increased and is expected to accelerate over the next few years as financial pressures are felt post-pandemic at the same time that these new therapies enter the marketplace at a greater pace. It has been strategically important to drive plan sponsor action for downstream vendor alignment, thus eliminating inefficiencies or waste in today's middleman-dominated system, which is not achieving value or improved quality at the member/patient level. That result is leading employers to address the question of whether they can get that necessary data and eliminate wasteful middlemen in the system we have today.

ALIGNING PATHWAYS–ADDRESSING PROBLEM AREAS

More complexity has occurred in US health care insurance through exclusions, prior authorization, shared patient out-of-pocket costs (copays, deductibles, coinsurance), rebates, patient assistance programs, accumulators, and maximizers. All that has resulted from today's escalation between key ecosystem stakeholders, is significantly reduced affordability, accessibility, and equity in commercial employer plans along with governmental plan offerings.

It becomes incumbent on employers, as the plan sponsor, to assess ways to better align the ecosystem to sustainably provide plan member access to these new durable, often curative, cell and gene therapies.

The assessment can easily start by accumulating exposure (patient use), as these therapies are personalized to very small patient cohorts and will therefore expose even the largest plans with only a handful of cases. Accumulating complex patients allows for "better" management to, as just one example, improve benefit determination with the appropriate precision diagnostics to achieve earlier/faster therapy starts. This example alone shows how the health plan can sustainably address many of the pressures on the patient and the diagnosing physician in today's ecosystem and significantly reduce direct and indirect costs borne by stakeholders.

Accumulating exposure also allows for greater predictability on patient use. This allows reinsurance to structure better ways to finance the cost and reduce the financial impact on any one plan sponsor. Reinsurance also has a history of developing sustainable resources to manage responses to unique and complex cases that can be embedded and accessible through

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the local plan. It is possible to have this relationship extend a patient's time in one employer plan and make the essential clinical pathway portable for the entire patient journey, meeting the requirements of a modern lab around patients treated with a gene and cell therapy to leverage data to put the patient in the position to optimize their outcome, which can be fairly assessed by the ecosystem.

This work and related questions are part of more recent transformation efforts specifically around health insurance by Turtle Grass LLC, Employer-Provider Interface Council, and others. Some examples of what "better" insurance can look like in answering the problems of today's market include:

- Affordable, equitable access to therapies by removing patient copays
- Improve prior authorization from weeks to hours, reducing provider frustrations
- Patient assistance not needed from manufacturers
- Redeploy and reduce money taken by utilization management in the current ecosystem

Next Steps

A call to action is an opportunity for employer plans and others to explore resourcefully combining various ecosystem value contributions for durable, curative high-cost therapies. There is a multistakeholder consortium seeking to use collaboration to create a patient-centric solution that capitalizes on current expenditures to produce value-driven services for the full patient journey. By utilizing comprehensive pathways aligned with benefits strategy, personalized medicine has the potential to enable each patient to receive earlier diagnoses, risk assessments, and optimal treatments. In our next column, we will continue to look at clinical pathways from the employer perspective and the role(s) of genomics in care pathways. Reader questions, feedback, and suggestions are always welcome and can be directed to JCPEditors@hmpglobal.com. ◆