Navigating Personalized Medicine: Challenges and Opportunities for Employer Plans

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The July/August 2023 edition of this column began to identify or explain how expensive gene and cell therapies are forcing change. Here we will further explore ways to address access to these therapies that are transforming management of benefits by employer plans. This transition from "drug" to "therapy" management requires different funding strategies and a greater focus around medical vs pharmacy benefit management solutions based on the patient care journey.

GROWTH IN PERSONALIZED MEDICINE THERAPIES

It has become increasingly important to clearly differentiate expensive, more durable biologics or curative therapies from small molecule pharmacy benefit drugs utilized in care for patients covered by insurance plans. Personalized drugs of the precision medicine era are the next phase of pharmaceutical industry innovation. These novel therapies comprised more than one third of all drug approvals in 2021 and 2022, and greater than 25% over the past seven years. Examples include several CAR-T cell therapies for previously incurable cancers, treatment for generalized myasthenia gravis, and several treatments for rare pediatric diseases (eg, Duchenne muscular dystrophy, Pompe's disease) caused by faulty genetics of inborn metabolism. While uncommon and previously untreatable, these disease examples today represent a range of catastrophic medical conditions that have treatment options. Unfortunately, those options may also lead to financial catastrophe for both the afflicted family and for the self-insured employer covering that member and dependents.

The traditional dogma in health insurance benefits design for self-insured employers has been that judicious health screening and preventive action programs yield a positive return on investment, both in direct medical and indirect productivity costs/gains. Can this be true for genomic screening and testing for personalized medicine therapies? For all impacted diseases of genetic origin taken together, the aggregate answer is unknown today. In rare pediatric conditions, an ability to have access to whole exome sequencing in most metropolitan areas does reduce the diagnostic odyssey and cost of (and time to) diagnosis for many patients. For the narrower category of cancer care, evidence is rapidly growing that analyzing cancer tissue genomics for targeted therapy guidance with personalized medicines avoids medical waste, improves patient outcomes, and saves total cost of care dollars.

The cost of genomic testing has continued to decrease substantially over time. The National Human Genome Research Institute has plotted the cost per genome over time, which over the past 20 years surpasses Moore's Law in microchips in terms of rate of cost decline. CMS reimbursement today for a comprehensive genomic profile of cancer (>50 genes) is $2919. Similarly, whole exome sequencing and related genomic deep dives are commercially available at reasonable pricing for a variety of needs across the precision medicine spectrum. In cancer, clinical utility and reliability of testing (knowing that the test gives reproducible results, and that those results matter) has improved to the point where the National Cancer Care Network has genomic testing standards for almost all cancers. When, as an example, testing for the right targeted therapy represents less than 3% of the average cost of care for annual active cancer treatment, the issue then becomes "Why aren't we testing appropriately?"

CARE COVERAGE AND EMPLOYER PLAN IMPACTS: ACTUARIAL MODELS FOR APPLICATION OF PRECISION MEDICINE PRINCIPLES

Precision medicine therapies frequently halt the progression of a disease, with some therapies being curative, and some allowing for a functional improvement and lower medical costs associated with the disease outside of drug therapy costs. Cancer is fast becoming a chronic disease, and an expensive disease, with 1.7 million Americans diagnosed every year, 600 000 dying, and costing $208.9 billion in 2022. While this equates to $42 000 per cancer patient annually while in treatment, some therapies can cost greater than $1 million per year.

Employees and their families who have cancer and other high-need conditions do not tend to change their insurance status, which in the commercial market means that they stay with their employer. In an MIT study of the length of time patients with high-cost and high-need chronic conditions typically stay in a health insurance plan, 70% of self-insured high-need patients were still with the same plan after 5 years. The management task of a third-party administrator then becomes one of understanding disease natural history over many

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years, and management in this paradigm. This represents both a dilemma and an opportunity to change how these conditions are managed from an insurance risk perspective.

A self-insured health plan can manage their high-cost and high-need patients who require personalized medicine therapies beyond one-year increments when an actuarial model is put in place. This model allows for an accounting of pharmacy, medical, lab, radiology, and other costs, as well as the indirect costs of loss of productivity and dependency. Early and thoughtful interventions that are focused on the specific disease and precision medicine therapy in a coordinated manner will reduce total costs. This yields a "net-net" positive return on investment when compared to unmanaged conditions requiring a precision medicine intervention.

Such a mutually beneficial, strategic outcome is particularly true over time increments of greater than one year. It also sets up the data framework and management conditions to allow for aggregated risk sharing across a condition with a pharmaceutical manufacturer. Their aligned interest is in best patient outcomes with best market penetration, using holistic data that comes from a total cost of care actuarial approach.

SUMMARY

Advances in personalized medicine have advanced beneficial treatment outcomes while pressuring the care and financial management of contemporary health insurance plans. Traditional benefit management, key performance indicators reported to employer plans, and financial coverage strategies need transformation in the face of personalized medicine. While emerging, there is a more urgent need addressing known gaps, modeling alternative structures, and determining predictive trends based on care pathways or journeys. Some progressive employers are already exploring how best to combine various health delivery and financial ecosystem value contributions for affordably covering the pipeline of emerging durable, curative high-cost therapies.

Utilizing comprehensive pathways aligned with benefits strategy through actuarial models could allow personalized medicine to reach its potential. Enabling each patient to receive earlier diagnoses, risk assessments of clinical or financial issues, and optimal treatments can be beneficial to all concerned.

In our next column, we will continue care pathways from the perspective and role(s) of employer plans that intersect with clinical pathways. Reader questions, feedback, and suggestions are always welcome and can be directed to JCPEditors@hmpglobal.com. ◆