


 Q CASE STUDY

## Pipeline Research and Policy Recommendations to Address New Innovative Therapies

### THE CLIENT

Large national pharmaceutical manufacturer government affairs team focused on innovative therapies, including cell and gene therapies.

### BACKGROUND

The client was looking for an experienced team who could assess the current pipeline of innovative therapies, examine current reimbursement policies to assess long-term compatibility with the adoption of innovative therapies and novel delivery mechanisms, and make policy recommendations to address any challenges identified through the process. HMA, The Moran Company, and Leavitt Partners, both HMA subsidiaries, were selected as the team with the needed expertise and capacity to create several deliverables. These deliverables were focused on the impact of the upcoming pipeline of certain innovative therapies on different payment systems, as well as working with the client's team to develop and refine federal and state policy recommendations to address identified challenges.

### RESULTS

The project equipped the client with a holistic understanding of future potential impacts and actions to address challenges in a detailed pipeline analysis of innovative therapies.

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### APPROACH

Our collective team developed the following qualitative and quantitative analyses:

- » Pipeline analysis of near-term innovative therapies
- » Analysis of this pipeline's interaction with current Medicare payment systems
- » Site of services for delivery of therapies and movement across payment systems
- » Overview of FDA oversight of cell and gene therapy
- » Medicaid reimbursement and budgetary issues resulting from pipeline of therapies
- » Payment system capacity issues analysis
- » Development and refinement of policy program recommendations

**Pipeline analysis.** With the pipeline analysis, the team assessed the types of products and stage of development before undertaking research on characteristics of individual therapies potentially entering the market. Data on potential new products was then stratified to allow for further analysis of key characteristics, such as patient population, type of clinical treatment, acute and chronic use, sites of service, and type of effect of the treatment.

**Payment system impacts.** The payment analyses included a combination of quantitative and qualitative sources to project the impacts of the pipeline on Medicare and Medicaid, as well as other impacts on payment system capacity.

**Policy recommendations.** After completing analyses on the different areas of payment impacts resulting from the pipeline of potential therapies, the team developed more than two dozen policy recommendations that could prepare, and further improve, existing payment systems for the pipeline of expected therapies. The team also identified potential strategies to educate policymakers and advance policies. Recommendations included policies related to Medicaid, Medicare, and value-based payments.