BACKGROUND

If the health care system is to secure the full benefits of personalized medicine, it must provide appropriate access to technologies, products, and services that make getting the best treatment option to each patient possible based on individual characteristics and circumstances. To help ensure equitable access, the reimbursement system must have evidence-based coverage and payment policies that support the timely adoption of validated personalized medicine technologies, including both diagnostics and therapeutics.

Payers are increasingly considering coverage and reimbursement of personalized medicine products and services both in the U.S. and internationally. However, there remain significant challenges in establishing coverage policies and payment rates for diagnostic tests and targeted therapeutics that reflect the value of their care. As a result, many novel diagnostics are under-reimbursed or not reimbursed at all, and targeted therapies are often subject to utilization management practices such as step therapy or prior authorization. Such practices ultimately restrict patient access to needed tests and optimal care. Coverage and reimbursement policies vary widely among different payers and laboratory benefits managers, and decision-making processes are often inconsistent and not transparent. Thus, it is not clear whether the broader payer community supports the move towards personalized medicine.

A better understanding of how payers view personalized medicine will help clarify the extent to which it has informed payer policies and perspectives globally and help identify remaining needs, which, in turn, will help product developers understand the payer landscape and the challenges they face.

OBJECTIVE

This project will involve an examination of varying policies and perspectives in order to capture a global picture of the coverage and reimbursement of personalized medicine services and technologies by public and private payers. The landscape analysis will include a representative sample of public and private health insurers, as well as large employers and laboratory benefit managers, and will include both quantitative and qualitative results to ensure that a global health system-wide payment picture of personalized medicine is captured. The results will be included in a report whose purpose will be to provide key personalized medicine stakeholders, including product developers, clinical laboratories, health care providers, payers, patients, and policymakers with information about access to personalized medicine technologies as related to the payment environment, thus informing payer-related strategies that may lead to improved access to personalized medicine.
**PROJECT OUTLINE**

The project, to be completed in six months, will involve the development of a framework to be used to measure personalized medicine coverage and reimbursement levels by government-run and private health insurers, as well as large employers.

The framework will be based on publicly available data showing payer coverage and utilization management policies, as well as payment details. It will also include survey data highlighting payer perspectives, partnerships, and practices related to personalized medicine.

In order to help ensure a holistic global view of the landscape of personalized medicine coverage and reimbursement, the analysis will focus on a representative sample of public and private payers and payment manager organizations including: large and small private health insurers; national and state-run public health plans; large employers with managed employee health benefits; and laboratory benefit manager organizations.

A project steering committee consisting of PMC members across payer, provider, industry, and patient stakeholder groups will guide the project, review survey questions, track progress at various milestones, and ensure an appropriate sample of survey respondents.

**CONCLUSION**

Many organizations within the personalized medicine community have called for an analysis of the current landscape of payer perspectives and policies on personalized medicine in the U.S. and internationally. This proposal is PMC’s answer to that call. We invite your sponsorship of this important project. Interested institutions should contact Daryl Pritchard (dpritchard@personalizedmedicinecoalition.org).

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**About the Personalized Medicine Coalition**

The Personalized Medicine Coalition (PMC), headquartered in Washington, DC, representing innovators, scientists, patients, providers and payers, promotes the understanding and adoption of personalized medicine concepts, services and products to benefit patients and health systems.