Introduction

Pharmacogenomics (PGx) is the study of how a person's genetic makeup can affect their response to a drug. PGx data can play an important role in identifying responders and non-responders to medications, avoiding adverse events and optimizing drug dose, and it is therefore an important tool to safely manage patient medications.[1] Currently, testing is *routine* only for certain conditions, such as HIV and some cancers, but integrating PGx results into other commonly prescribed medications like opioids, anti-depressants and cardiac medications can reduce cost and improve patient outcomes through comprehensive medication management (CMM).[2]

Each year, 275,000 people die needlessly and $528.4 billion a year is wasted due to non-optimized medication use.[3] Evaluating a patient's genetics to support the clinical-decision making process ensures a more precise and personalized approach and is a tool that will continue to have increased demand through published guidelines, research, clinician and patient education and advocacy. To maximize medication optimization, we need to integrate PGx into the process of CMM. Genetic testing, along with other factors such as lifestyle, environment and comorbidities should be incorporated into CMM team-based care. PGx offers the potential to personalize treatment and care of individuals, increase patient satisfaction and physician confidence, decrease costs and optimize medication therapy.

Below are recommendations that policymakers should consider to ensure that patient medications are managed safely and effectively based on the unique characteristic of an individual patient's genetic profile.

PGx Payment Policy Recommendations from the GTMRx Institute:

1. Establish coverage for regular assessment of patient medications and drug-gene interactions for Medicare and Medicaid beneficiaries:
    a. Direct CMS to modernize the "Welcome to Medicare" preventive visit by including access to pharmacogenomic testing and associated comprehensive medication management informed by such testing.

[1] Table of Pharmacogenomic Biomarkers in Drug Labeling. U.S. Food and Drug Administration. Accessed Sept. 6, 2020. https://www.fda.gov/ drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling
[2] CMM is a systematic approach to medications where physicians and pharmacists ensure that medications (whether they are prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements) are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended. (McInnis T, Webb E, and Strand L. The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes, Patient Centered Primary Care Collaborative. June 2012.).
[3] Watanabe J, et al. "Cost of Prescription Drug–Related Morbidity and Mortality." Annals of Pharmacotherapy, March 26, 2018. journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full.

   b. Allow clinicians to assess the need for pharmacogenomic testing and comprehensive medication management informed by such testing, as part of the "Welcome to Medicare" preventive visit.
   c. Update the yearly "Wellness" visit to include a comprehensive medication management assessment by a member of the patient's care team trained to evaluate and manage medications based on the patient's genotype, disease states, multi-drug interactions and other factors that influence drug metabolism, effectiveness and risk.[4]
   d. Direct CMS to allow patients to access pharmacogenomic testing and comprehensive medication management during diagnostic, screening and preventative services covered through Medicaid annual preventive care visits.
   e. Direct HHS to develop a reference resource about drug-gene interactions, including when to refer patients to a member of the comprehensive medication management care team trained to evaluate factors influencing the effectiveness of medications including pharmacogenomic results.

2. Require Medicare and Medicaid to reimburse preemptive multi-gene panel testing as one single test with one standard compensation code when a physician or clinical pharmacist, in coordination with the comprehensive medication management care team, can demonstrate clinical utility, and require that results be entered into a patient's EHR for medical use throughout the patient's lifetime to prevent avoidable patient harm and improve patient health outcomes.

3. Establish reimbursement within Medicare and Medicaid for members of the care team, including clinical pharmacists, with residency, certificate or continuing education training to evaluate and manage medications based on the patient's genotype, disease states, multi-drug interactions and other factors that influence drug metabolism, effectiveness and risk, including clinical pharmacists when ordering and interpreting pharmacogenomic tests and when providing comprehensive medication management services, including management and follow-up of laboratory results and drug-gene interactions.
   a. Direct Medicare and Medicaid to reimburse for these services, including when they are provided via telehealth.

[4] The FDA has indicated that genotype should be considered in combination with other factors that influence drug metabolism. "In particular, each patient's genetic makeup is only one of many factors that may impact drug concentrations and response, highlighting the fact that information provided in this table is limited to certain pharmacogenetic associations only and does not provide comprehensive information needed for safe and effective use of a drug. Accordingly, health care providers should refer to FDA-approved labeling for prescribing information, including monitoring instructions and information on other factors that may affect drug concentrations, benefits, and risks." (FDA Table of Pharmacogenomic Associations, https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations#about, Accessed 4/6/2021).

4. Direct CMS to coordinate the development of pharmacogenomic quality measures to be reviewed and endorsed by the National Quality Forum (NQF).

5. Recommend that the U.S. Preventive Services Task Force evaluate evidence of pharmacogenomic testing and comprehensive medication management for drugs with known drug-gene interactions as a preventive health care practice that addresses patient outcomes and medical expenditures and that should be covered by Affordable Care Act (ACA) plans.

Developed by the GTMRx PGx Payment and Policy Solutions Taskforce and the GTMRx Payment and Policy Solutions Workgroup

- Tom Kraus, JD, MHS, Vice President, Office of Government Relations, American Society of Health-System Pharmacists
- Brian Litten, JD, Chief Strategic Growth Officer, Tabula Rasa HealthCare
- Bayli Larson, Pharm.D., M.S., BCPS, Strategic Initiatives Associate, Office of the Chief Operating Officer and Senior Vice President, American Society of Health-System Pharmacists
- Kathy Pham, Pharm.D., BCPPS, Director of Policy and Professional Affairs at the American College of Clinical Pharmacy
- John McGlew, MA, Director, Government Affairs, American College of Clinical Pharmacy
- Brad Cannon, Pharm.D., Director of Experiential Education, Assistant Professor, Rosalind Franklin University of Medicine and Science; Speaker of the House of Delegates and Member, Board of Directors, American Association of Colleges of Pharmacy