PERSONALIZED MEDICINE COALITION

December 20, 2024

Dr. Anne Docimo
Chief Medical Officer

Dr. Lucy Langer
National Medical Director of Oncology and Genomics

Dr. Donald Tavakoli
National Medical Director, Behavioral Health

UnitedHealthcare
5901 Lincoln Drive
Saint Louis Park, MN 55436

Delivered electronically

Dear Drs. Docimo, Langer and Tavakoli:

On behalf of the Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions and individuals from across the health care spectrum, I am writing regarding UnitedHealthcare (UHC)'s recent revision of its Pharmacogenetic Panel Testing Policy[i]. Since 2019, UHC members have benefited from clinically useful pharmacogenetic (PGx) tests for selecting effective treatments for mental health conditions. Beginning on January 1, 2025, the revised policy would remove longstanding coverage for "multi-gene" PGx panel tests that can help guide patients as efficiently as possible toward effective treatments for major depressive disorder and anxiety and will continue lack of coverage for multi-gene pharmacogenetic panels for other areas of therapy based on the number of genes rather than their clinical utility. This is concerning, and UHC should reconsider implementation.

Statement of Neutrality
Many of PMC's members may present their own responses to UHC's Pharmacogenetic Panel Testing Policy. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance and are not intended to adversely impact the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to this policy or related issues.

Background
PMC defines personalized medicine as a field in which physicians use diagnostic tests and individual details about a person and their health to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By

combining data from diagnostic tests with an individual's medical history, circumstances and values, health care providers can develop targeted treatment and prevention plans with their patients. Personalized medicine is helping to shift patient and provider experiences away from trial-and-error treatment of late-stage diseases in favor of more streamlined approaches to disease prevention and treatment.

Pharmacogenetics is a cornerstone of personalized medicine and holds enormous potential for improving therapeutic decision-making and therapeutic response, as well as decreasing adverse reactions. An analysis of the real-world use of PGx testing and active medication management demonstrated improvements in patient outcomes and lower health care costs.[ii] Randomized trials to date also show a significant reduction in adverse events when multi-gene PGx panels are utilized to guide treatment.[iii] The availability of tests that accurately and reliably identify variations in genes that account for differences in drug response is critical to the success of pharmacogenetics. Where appropriate evidence exists for coverage of such tests, treating providers and the patients they serve should have access to them. UHC had previously been a leader in providing access to PGx panel testing services for its members for major depressive disorder and generalized anxiety disorder. However, sudden revision of the current Pharmacogenetic Panel Testing Policy sets a troublesome precedent.

Call for reconsideration

We are unaware of an example where a commercial payer has rescinded longstanding coverage for a class of tests in the absence of new data indicating harm to patients. PMC is concerned about the loss of patient and provider access resulting from this sudden policy reversal as well as the impact this decision may have on continued investment in personalized medicine. Therefore, we respectfully request that UHC reconsider implementation of this revised policy on January 1, 2025.

Please feel free to contact me at cbens@personalizedmedicinecoalition.org or David Davenport, PMC's Director of Science and Public Policy, at ddavenport@personalizedmedicinecoalition.org with any questions.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

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[i] UnitedHealthcare. Commercial and Individual Exchange Medical Policy Pharmacogenetic Panel Testing. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/index/commercial/pharmacogenetic-panel-testing-01012025.pdf

[ii] Jarvis, J.P.; Peter, A.P.; Keogh, M.; Baldasare, V.; Beanland, G.M.; Wilkerson, Z.T.; Kradel, S.; Shaman, J.A. Real-World Impact of a Pharmacogenomics-Enriched Comprehensive Medication Management Program. J. Pers. Med. 2022, 12, 421. https://doi.org/10.3390/jpm12030421

[iii] Swen, Jesse JBuunk, Annemarie et al. A 12-gene pharmacogenetic panel to prevent adverse drug reactions: an open-label, multicentre, controlled, cluster-randomised crossover implementation study. The Lancet, Volume 401, Issue 10374, 347 – 356. https://doi.org/10.1016/S0140-6736(22)01841-4