

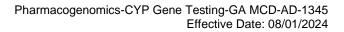
ADMINISTRATIVE POLICY STATEMENT Georgia Medicaid Policy Name & Number Pharmacogenomics-CYP Gene Testing-GA MCD-AD

Date Effective

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A. Subject Pharmacogenomics- CYP Gene Testing

B. Background

Pharmacogenomics is an area of precision medicine that provides information about an

benefit or toxicity to a given drug. This form of medication management has been evaluated in a variety of clinical scenarios. As pharmacogenomics expands and laboratories offering testing proliferate, the value of a given test in terms of patient benefit may be obscured by multiple contributing factors, including exaggerated public marketing claims, inconsistencies in test standardization, continued patient variation in response to prescribed medication, incomplete knowledge of drug metabolism, and limitations in regulatory oversight. To manage these challenges, the clinical validity and clinical utility of a specific gene or biomarker with a specific drug target should demonstrate improvement in patient outcomes.

C. Definitions

- **Clinical Utility** The likelihood that a test will, by prompting an intervention, result in an improved health outcome.
- **Clinical Validity** The accuracy of a test for a given clinical outcome.
- Unbundling HCPCS/CPT codes should be reported only if all servBT/F1 9f1 ervBT[(g)] TJETQq0



CPT® Codes	Testing Examples
81225 - CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19)	Genecept Assay,
(eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)	OneOme
81226 - CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg,	RightMed,
drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9,	PGxOnePlus,
*10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)	CQuentia,
81227 - CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9) (eg,	IDGenetix,
drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)	PROOVE,
81230 - CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug	GARSPREDX,
metabolism), gene analysis, common variant(s) (eg, *2, *22)	PharmacoDx

- III. The following codes require review by CareSource and authorization prior to service provision:
 - A. 81291 MTHFR (5, 10-methylenetetrahydrofolate reductase) (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
 - B. 0345U Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6

IV. CareSource applies coding edits to medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. Proper billing and submission guidelines must be followed, including the following:

- A. Use of iAQUSEB/Tstandarc,1compliantTcodes on 26.claise4s290 Trissions. Ginologiog Tc[(D.)] TJETQq/ CPT codes and/or HCPCS codes.
- Β.

primary service rendered are not allowed additional payment.

- C. Proprietary panel testing requires evidence-based documentation of medical necessity.
- D. Submission of the most accurate and appropriate CPT/HCPCS code(s) for the product or service being provided, including coding to the highest level of specificity.
- V. CareSource considers the following not medically 12 0 612 BT/F1311. 612 BT/F1311. 612 BT/F1311



- 11. Clinical Utility Evaluation: MTHRF Genetic Testing for Nondevelopmental Psychiatric Disorders. Hayes; 2023. Accessed March 14, 2024. www.hayesinc.com
- 12. Clinical Utility Evaluation: MTHRF Genetic Testing for Pregnancy Complications. Hayes; 2023. Accessed March 14, 2024. www.hayesinc.com
- 13. Clinical Utility Evaluation: MTHRF Genetic Testing for Severe MTHFR Enzyme Deficiency. Hayes; 2023. Accessed March 14, 2024. www.hayesinc.com
- 14. Clinical Utility Evaluation: MTHRF Pharmacogenetic Genotyping for Altering Drug Treatment. Hayes; 2017. Updated May 23, 2021. Accessed March 14, 2024. www.hayesinc.com
- 15. Clinical Utility Evaluation: Pharmacogenetic and Pharmacogenomic Testing for Opioid Treatment for Pain in Adults Selected Single-Gene Variants and Pharmacogenomic Panels. Hayes; 2019. Updated October 26, 2022. Accessed March 14, 2024. www.evidenced.hayesinc.com
- Clinical Utility Evaluation: Pharmacogenetic and Pharmacogenomic Testing to Improve Outcomes Related to Opioid Use Disorder. Hayes; 2020. Updated June 30, 2023. Accessed March 14, 2024. www.evidence.hayesinc.comnc.com