ADMINISTRATIVE POLICY STATEMENT
Georgia Medicaid

Policy Name & Number	Date Effective
Pharmacogenomics-CYP Gene Testing-GA MCD-AD-1345	08/01/2024-12/31/2024
Policy Type	
ADMINISTRATIVE	

Administrative Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Administrative Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Administrative Policy Statement. If there is a conflict between the Administrative Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject
Pharmacogenomics- CYP Gene Testing

B. Background
Pharmacogenomics is an area of precision medicine that provides information about an individual's genes, influencing therapeutic strategies and assessing the likelihood of 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 services described by the code are performed. Multiple codes should not be reported if a single code exists that describes the services performed. The codes include all services usually performed as part of the procedure as a standard of medical/ surgical practice and should not be separately reported simply because codes exist for the services.

D. Policy
I. General Guidelines
A. Biomarker testing with uncertain clinical significance in MCG Health will be considered experimental and investigational.
B. Unbundling of codes in a panel is an incorrect billing practice and will result in payment recovery.
C. Any drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply used in or directly related to the diagnosis, evaluation, or treatment of a disease, injury, illness, or other health condition which CareSource determines in its sole discretion to be experimental or investigational is not covered by CareSource.

II. Based on review of existing evidence, there are currently no clinical indications for the high-volume tests below, and the current role remains uncertain. Therefore, CareSource considers these requests experimental and investigational, as there is not sufficient evidence for use in the peer reviewed literature. This is not an all-inclusive list.

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

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 industry standard, compliant codes on all claims submissions, including CPT codes and/or HCPCS codes.
   B. Services considered to be mutually exclusive, incidental to or integral to the 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 necessary (not an all-inclusive list):
   A. Pharmacogenomic testing or screening in the general population.
   B. A non-covered test billed by using unlisted procedure codes.
   C. The use of multi-gene panels for genetic polymorphisms, including, but not limited to, pain management, cardiovascular drugs, anthracyclines, or polypharmacy for evaluating drug-metabolizer status (eg, PharmacoDx).
   D. Tests considered screening in the absence of clinical signs/symptoms of disease.
   E. Tests that do not confirm new data for decision making but confirm a known diagnosis or information.
   F. Tests to determine risk for developing a disease or condition.
   G. Tests without diagnosis-specific indications.
   H. Tests performed to ensure a tissue specimen matches an individual.

E. Conditions of Coverage

Codes referenced in this policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage.

F. Related Policies/Rules

Medical Necessity Determinations
Overpayment Recovery
Experimental and Investigational Item and Service

G. Review/Revision History

	DATE	ACTION
Date Issued	04/26/2023	Approved at Committee.
Date Revised	03/27/2024	Removed 0345U & 81291 from chart in D.II. Approved at Committee.
Date Effective	08/01/2024	
Date Archived	12/31/2024	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

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