Pharmacogenomics Testing

Humana

Medicaid Medical Coverage Policy

Original Effective Date: 04/01/2025
Effective Date: 06/25/2025
Review Date: 04/01/2025
Policy Number: HUM-2240-000
Line of Business: Medicaid
State: OH

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Scope

This policy applies to all physical and behavioral health prior authorization requests received by Humana Healthy Horizons™ in Ohio.

Policy

Humana Healthy Horizons™ in Ohio uses established criteria guidelines to make medical necessity decisions and follows the below procedure. Decisions are made on a case-by-case basis, utilizing the information provided about the member's health status and an assessment of the local delivery system. Emergent services do not require a referral or preauthorization.

The Plan covers all benefits and services required in Ohio Administrative Code (OAC) chapter 5160 in the amount, duration, and scope for the same services furnished to members under the fee-for-service (FFS) Medicaid.

When the plan receives a request for a primary code that requires prior authorization and the primary code is denied for lack of medical necessity, any related secondary codes submitted on the authorization request will be denied based on lack of medical necessity. When a primary code is approved, related secondary codes requiring prior authorization will be reviewed individually for medically necessity determinations.

Please see Ohio Medicaid Prior Authorization and Notification List for a list of CPT and HCPCS codes that require prior authorization.

Humana Healthy Horizons™ in Ohio will review requested non-MCO covered codes and services as required for Early and Periodic Screening, Diagnostic and Treatment (EPSDT) for medical necessity to ensure children and adolescents receive appropriate and preventative, dental, mental health, developmental and specialty services.

Humana Healthy Horizons™ in Ohio does not cover services, items or devices that have not been approved by the Food and Drug Administration (FDA). Other factors affecting reimbursement supersede this policy. These factors include but are not limited to Federal and/or State statutes and regulations, the State Plan, the MCE Manual, physician or other provider contracts, the beneficiaries' benefit coverage documents, and/or other reimbursement, medical or drug policies.

Providers may submit authorization request(s) through the provider portal. A provider may request an urgent prior authorization in situations where the provider considers a delay in providing services, supplies or prescription drugs requiring prior authorization to be detrimental to the health of the member. The absence of authorization and/or notification prior to the date of a service could result in financial penalties for the practice and reduced benefits for the member, based on the healthcare provider's contract and the member's Certificate of Coverage. Services or medications provided without preauthorization may be subject to retrospective medical necessity review. We recommend individual practitioners making specific requests for services or medications verify benefits and preauthorization requirements with Humana prior to providing services.

Medical necessity documentation and rationale must be submitted with the prior authorization request. Providers may access physical and behavioral clinical coverage policies and medical necessity criteria at the below links.

Physical Health:
www.humana.com/provider/medical-resources/ohio-medicaid/physical-health-clinical-coverage-policies

Behavioral Health:
www.humana.com/provider/medical-resources/ohio-medicaid/behavioral-health-clinical-coverage-policies

Members may request a copy of the medical necessity criteria by calling member services at 877-856-5702 (TTY:711), Monday-Friday, 7AM to 8PM EST.

Providers may request a copy of the medical necessity criteria by calling provider services at 877-856-5707 (TTY:711), Monday-Friday, 7AM to 8PM EST or emailing the request to ODMCDUM@humana.com.

Procedures

1. The Plan uses the following hierarchy of guidelines to review for medical necessity:
   1.1 Federal or state regulation, including medical criteria published in the Ohio

Administrative Code, Chapter 5160.

1.2 Nationally accepted evidence based clinical guidelines: MCG (formerly Milliman Care Guidelines), American Society of Addiction Medicine (ASAM) Level of Care Adolescent Guidelines and American Society of Addiction Medicine (ASAM) Patient Placement Criteria (ASAM Admission Guidelines).

1.3 Humana Healthy Horizons™ in Ohio clinical policies

1.4 In the case of no guidance from above, additional information that the clinical reviewer will consider, when available, includes;

- 1.4.1 Clinical practice guidelines and reports from peer reviewed medical literature, from which a higher level of evidence and study quality is more strongly considered in determinations;
- 1.4.2 Professional standards for safety and effectiveness recognized in the US for diagnosis, care, or treatment;
- 1.4.3 Medical association publications;
- 1.4.4 Government-funded or independent entities that assess and report on clinical care; Decision and technology such as Agency for Healthcare Research and Quality (AHRQ), Hayes Technology Assessment, Up-To-Date, Cochrane Reviews, National Institute for Health and Care Excellence (NICE), etc.;
- 1.4.5 Published expert opinions;
- 1.4.6 Opinion of health professionals in the area of specialty involved;
- 1.4.7 Opinion of attending provider;

1.5 Dental: DentaQuest coverage guidelines and policies
Dental Coverage - Humana Healthy Horizons in Ohio | Humana

1.6 Vision: EyeMed coverage guidelines and policies
Vision Care - Humana Healthy Horizons - Ohio Medicaid | Humana

Description

Pharmacogenomics testing is laboratory testing which has the potential to determine how an individual's genetic factors may affect the safety and effectiveness of that individual's response to a specific medication. The goal of pharmacogenomics testing is to reduce the incidence of adverse medication reactions while improving an individual's positive response to the medication. Additionally, some tests may help provide information on how well a specific treatment may work for an individual.

Coverage Determination

***DPYD* Genotype Testing**

Humana members may be eligible under the Plan for ***DPYD* genotype testing (81232)** for either of the following indications:

- Guide medication dosing when performed prior to the initiation of fluoropyrimidine medication therapy (eg, capecitabine, fluorouracil)[9,44,57]; **OR**

- Severe or unexpected toxicity from fluoropyrimidine medication therapy (eg, capecitabine, fluorouracil)[44]

***NUDT15* and *TPMT* Genotype Testing**

Humana members may be eligible under the Plan for ***NUDT15* (81306) and/or *TPMT* (84433) genotype testing** for either of the following indications:

- Guide medication dosing when performed prior to the initiation of thiopurine medication therapy (eg, azathioprine, mercaptopurine, thioguanine)[1,13,34,36,57]; **OR**

- Severe toxicity from thiopurine medication therapy (eg, azathioprine, mercaptopurine, thioguanine)[36]

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for the following pharmacogenomics testing:

- Cytochrome P450 1A2 Genotype (0031U)
- EffectiveRX Comprehensive Panel (0438U)
- Genomind Pharmacogenetics Report – Full (0423U)
- *IFNL3* genotype testing (81283)
- MindX One Blood Test – Anxiety (0437U)
- Psych HealthPGx Panel (0173U)
- RightMed Comprehensive Test (0349U)
- RightMed Comprehensive Test Excludes F2 and F5 (0348U)
- RightMed Gene Report (0350U)
- RightMed Gene Test Excludes F2 and F5 (0434U)
- RightMed Oncology Medication Report (0461U)
- Serotonin Receptor Genotype (0033U)
- Tempus nP (0419U)

A review of the current medical literature shows that there is **no evidence** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Humana members may **NOT** be eligible under the Plan for the following pharmacogenomics testing:

- ChemoFx Assay (81535/81536)[6,27,35,45]
- CNT (CEP72, NUDT15 and TPMT) Genotyping Panel (0286U)[29]
- GeneSight Psychotropic test (0345U)

- Genomind Professional PGx Express CORE (0175U)[15,23,31,46,54,55]
- IDgenetix (0411U)
- Mayo Clinic Catechol-O-Methyltransferase (COMT) Genotype (0032U)[11]
- *SLCO1B1* genotype testing (81328)[24,37]
- *TYMS* genotype testing (81346)[9,44]

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
81232	DPYD (dihydropyrimidine dehydrogenase) (eg, 5-fluorouracil/5-FU and capecitabine drug metabolism), gene analysis, common variant(s) (eg, *2A, *4, *5, *6)	
81283	IFNL3 (interferon, lambda 3) (eg, drug response), gene analysis, rs12979860 variant	
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)	
81328	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction), gene analysis, common variant(s) (eg, *5)	
81346	TYMS (thymidylate synthetase) (eg, 5-fluorouracil/5-FU drug metabolism), gene analysis, common variant(s) (eg, tandem repeat variant)	
81535	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination	
81536	Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)	
84433	Thiopurine S-methyltransferase (TPMT)	

0031U	CYP1A2 (cytochrome P450 family 1, subfamily A, member 2)(eg, drug metabolism) gene analysis, common variants (ie, *1F, *1K, *6, *7)	
0033U	HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G])	
0173U	Psychiatry (ie, depression, anxiety), genomic analysis panel, includes variant analysis of 14 genes	
0175U	Psychiatry (eg, depression, anxiety), genomic analysis panel, variant analysis of 15 genes	
0286U	CEP72 (centrosomal protein, 72-KDa), NUDT15 (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) (eg, drug metabolism) gene analysis, common variants	
0345U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	
0348U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 25 gene report, with variant analysis and reported phenotypes	
0349U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis, including reported phenotypes and impacted gene-drug interactions	
0350U	Drug metabolism or processing (multiple conditions), whole blood or buccal specimen, DNA analysis, 27 gene report, with variant analysis and reported phenotypes	
0411U	Psychiatry (eg, depression, anxiety, attention deficit hyperactivity disorder [ADHD]), genomic analysis panel, variant analysis of 15 genes, including deletion/duplication analysis of CYP2D6	
0419U	Neuropsychiatry (eg, depression, anxiety), genomic sequence analysis panel, variant analysis of 13 genes, saliva or buccal swab, report of each gene phenotype	
0423U	Psychiatry (eg, depression, anxiety), genomic analysis panel, including variant analysis of 26 genes, buccal swab, report including metabolizer status and risk of drug toxicity by condition	

0434U	Drug metabolism (adverse drug reactions and drug response), genomic analysis panel, variant analysis of 25 genes with reported phenotypes	
0437U	Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score	
0438U	Drug metabolism (adverse drug reactions and drug response), buccal specimen, gene-drug interactions, variant analysis of 33 genes, including deletion/duplication analysis of CYP2D6, including reported phenotypes and impacted gene-drug interactions	
0461U	Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

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Definitions

1. Adverse Benefit Determination – As defined in OAC rule 5160-26-01, is a managed care entity's (MCEs):
    G. Denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit;
    H. Reduction, suspension, or termination or services prior to the member receiving the services previously authorized by the MCE;
    I. Failure to provide services in a timely manner as specified in rule 5160-26-03.1 of the Administrative Code;
    J. Failure to act within the resolution timeframes specified in rule 5160-26-08.4 of the Administrative Code;
    K. Denial of a member's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other member financial liabilities, if applicable; or
    L. Denial, in whole or part, of payment for a service. A denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a "clean claim" as defined in 42 C.F.R. 447.45(b) (October 1, 2021) is not an adverse benefit determination).
2. American Society of Addiction Medicine (ASAM) – a professional medical society representing over 7,000 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM produces a comprehensive set of standards for placement, continued stay, transfer or discharge of patients with addiction and co-occurring conditions used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.
3. MCG – are nationally recognized guidelines used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.
4. Medically Necessary or Medical Necessity – Has the same meaning as OAC rule 5160-1-01:
    A. Medical necessity for individuals covered by early and periodic screening, diagnosis, and treatment (EPSDT) is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate, correct, ameliorate, or treat as adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability.
    B. Medical necessity for individuals not covered by EPSDT is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability and without which the person 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.
    C. Conditions of medical necessity for a procedure, item, or service are met all the following apply:
        a. It meets generally accepted standards of medical practice;
        b. It is clinically appropriate in its type, frequency, extent, duration, and delivery setting;
        c. It is appropriate to the adverse health condition for which it is provided and is expected to produce the desired outcome;
        d. It is the lowest cost alternative that effectively addresses and treats the medical problem;

e. It provides unique, essential, and appropriate information if it is used for diagnostic purposes; and
f. It is not provided primarily for the economic benefit of the provider nor for the sole convenience of the provider or anyone else other than the recipient.

D. The fact that a physician, dentist, or other licensed practitioner renders, prescribes, orders, certifies, recommends, approves, or submits a claim for a procedure, item, or service does not, in and of itself make the procedure, item, or service medically necessary and does not guarantee payment.
E. The definition and conditions of medical necessity articulated in this rule apply throughout the entire medicaid program. More specific criteria regarding the conditions of medical necessity for particular categories of service may be set forth within the Ohio Department of Medicaid (ODM) coverage policies or rules.

Change Summary

04/01/2025 New Policy.