Department: Utilization Management	**Policy and Procedure No:** MCD-OH-CLI-H1238	
Policy and Procedure Title: Breast Cancer Gene Expression Assays Medical Necessity		
Process Cycle: Annually	**Responsible Departments:** Clinical	
Approved By: Dr. Mark Rastetter	**Effective Date:** 2/1/2023	**Revised:**

POLICY AND PROCEDURE:

Policy:
Humana Healthy Horizons™ of Ohio will use established criteria guidelines to make medical necessity decisions on case-by-case basis, based on the information provided on the member's health status.

Procedure:
For Breast Cancer Gene Expression Assays services, Humana Healthy Horizons in Ohio uses MCG® criteria.

MCG® criteria is nationally recognized and URAC (Utilization Review Accreditation Commission) certified. It is proprietary and cannot be publicly published and/or distributed. On an individual member or provider basis, the specific medical necessity criteria will be made available upon request.

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

Providers may submit a request for medical necessity request by calling 877-856-5707 (TTY:711), Monday – Friday, from 7 a.m. to 8 p.m. EST or emailing the request to OHMCDUM@humana.com.

Related codes include, but are not limited to:

CPT® Code(s)	Description
81519	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score
81520	Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score
81522	Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score
81599	Unlisted multianalyte assay with algorithmic analysis
81521	Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis

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81523	Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis
81518	Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy
81554	Pulmonary disease (idiopathic pulmonary fibrosis [IPF]), mRNA, gene expression analysis of 190 genes, utilizing transbronchial biopsies, diagnostic algorithm reported as categorical result (eg, positive or negative for high probability of usual interstitial pneumonia [UIP])
CPT® Category III Code(s)	**Description**
	N/A
HCPCS Code(s)	**Description**
	N/A

1) The Plan covers all benefits and services required in OAC chapter 5160 in the amount, duration, and scope for the same services furnished to members under the fee-for-service (FFS) Medicaid.
2) When applying coverage policies and medical necessity criteria, the Plan will consider individual member needs and an assessment of the local delivery system.

3) The Plan uses the following hierarchy of guidelines to review for medical necessity:
    a) Federal or state regulation, including medical criteria published in the Ohio Administrative Code, Chapter 5160.
    b) 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)
    c) Humana Healthy Horizons in Ohio clinical policies
    d) In the case of no guidance from above, additional information that the clinical reviewer will consider, when available, includes:
        i. 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;

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ii. Professional standards of safety and effectiveness recognized in the US for diagnosis, care, or treatment;
iii. Medical association publications
iv. Government-funded or independent entities that assess and report on clinical care
v. decisions 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.;
vi. Published expert opinions;
vii. Opinion of health professionals in the area of specialty involved;
viii. Opinion of attending provider

e) Dental: DentaQuest coverage guidelines and policies
Dental Coverage - Humana Healthy Horizons in Ohio | Humana
f) Vision: EyeMed coverage guidelines and policies
Vision Care - Humana Healthy Horizons - Ohio Medicaid | Humana

Only practitioners with the appropriate clinical expertise can make the decision to deny or reduce the amount, duration or scope of the services being requested.

Humana Healthy Horizons™ in Ohio requires prior authorization on all “Miscellaneous”, “Unlisted”, “Not Otherwise Specified” codes. Medical necessity documentation and rationale must be submitted with the prior authorization request. The medical director adheres to the above process to align criteria based on the information provided on the member’s health status.

RESOURCES:

- Ohio Administrative Code 5160-1-01 Medicaid medical necessity: definitions and principles. Retrieved October 28, 2022, from https://codes.ohio.gov/ohio-administrative-code/5160
- MCG® https://www.mcg.com/care-guidelines/care-guidelines/

CONTRACT LANGUAGE:

5. Coverage Requirements

a. Medical Necessity Criteria

i. Pursuant to OAC rule 5160-26-03, the MCO's coverage requirements and decisions must be based on the coverage and medical necessity criteria published in OAC Chapter 5160 and practice guidelines as specified in OAC rule 5160-26-05.1.
ii. The MCO must have objective, written criteria based on sound clinical evidence to make medical necessity and utilization decisions. The MCO must involve appropriate providers in the development, adoption, and review of medical necessity criteria.

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The MCO's written criteria must meet NCQA standards and must specify procedures for appropriately applying the criteria.

iii. The MCO must use ODM-developed medical necessity criteria where it exists. In the absence of ODM-developed medical necessity criteria, the MCO must use clinically-accepted, evidence-informed medical necessity criteria (e.g., InterQual®, MCG®, and ASAM) as approved by ODM.

iv. In the absence of ODM-developed medical necessity criteria or ODM-approved, clinically-accepted, evidence-informed medical necessity criteria, the MCO's adaptation or development of medical necessity criteria must be based upon evaluated, peer reviewed medical literature published in the United States.
   1. Peer reviewed medical literature must include investigations that have been reproduced by non-affiliated authoritative sources.
   2. The literature must also include positive endorsements by national medical bodies or panels regarding scientific efficacy and rationale that is based upon well-designed research and endorsements by national medical bodies or panels regarding scientific efficacy and rationale.

v. When applying coverage policies and medical necessity criteria, the MCO must consider individual member needs and an assessment of the local delivery system.

DEFINITIONS:

Adverse Benefit Determination – As defined in OAC rule 5160-26-08.4, a Managed Care Organization's (MCO's):

a. 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;
b. Reduction, suspension, or termination of services prior to the member receiving the services previously authorized by the MCO;
c. 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” is not an adverse benefit determination);
d. Failure to provide services in a timely manner as specified in OAC rule 5160-26-03.1;
e. Failure to act within the resolution timeframes specified in this rule; or
f. Denial of a member's request to dispute a financial liability, including cost sharing, co-payments, premiums, deductibles, coinsurance, and other member financial liabilities, if applicable.

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 addition 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.

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MCG® – Formerly known as Milliman Care Guidelines, 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.

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 defined as procedures, items, or services that prevent, diagnose, evaluate, correct, ameliorate, 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.
b. Medical necessity for individuals not covered by EPSDT is defined as 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 are met if all the following apply:
    i. It meets generally accepted standards of medical practice;
    ii. It clinically appropriate in its type, frequency, extent, duration, and delivery setting;
    iii. It is appropriate to the adverse health condition for which it is provided and is expected to produce the desired outcome;
    iv. It is the lowest cost alternative that effectively addresses and treats the medical problem;
    v. Provides unique, essential, and appropriate information if it is used for diagnostic purposes; and
    vi. It is not provided primarily for the economic benefit of the provider nor for the 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 for it.
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 ODM coverage policies or rules.

VERSION CONTROL

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Version Review Approval History				
Department:	**Purpose of Review**	**Reviewed and Approved By:**	**Date:**	**Additional Comments:**
Clinical	Policy Development	Dr. Mark Rastetter	12/11/2022	

DISCLAIMER:

Humana follows all federal and state laws and regulations. Where more than one state is impacted by an issue, to allow for consistency, Humana will follow the most stringent requirement.

This document is intended as a guideline. Situations may arise in which professional judgment may necessitate actions that differ from the guideline. Circumstances that justify the variation from the guideline should be noted and submitted to the appropriate business area for review and documentation. This (policy/procedure) is subject to change or termination by Humana at any time. Humana has full and final discretionary authority for its interpretation and application. This (policy/procedure) supersedes all other policies, requirements, procedures or information conflicting with it. If viewing a printed version of this document, please refer to the electronic copy maintained by CMU to ensure no modifications have been made.

NON-COMPLIANCE:

Failing to comply with any part of Humana's policies, procedures, and guidelines may result in disciplinary actions up to and including termination of employment, services or relationship with Humana. In addition, state and/or federal agencies may take action in accordance with applicable laws, rules and regulations.

Any unlawful act involving Humana systems or information may result in Humana turning over all evidence of unlawful activity to appropriate authorities. Information on handling sanctions related to non-compliance with this policy may be found in the Expectations for Performance, and Critical Offenses policies, both of which may be found in the Associate Support Center via Humana's secure intranet of Hi! (Workday & Apps/Associate Support Center).