OH.CLI.1379 Gene Expression Profiling for Cancer Indications

Effective Date:	January 12, 2024	Accountable Dept.:	Medicaid Clinical Delivery Experience 10585
Last Reviewed Date:	November 28, 2023		

Summary of Changes:

None – new policy created H1379.

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 use established criteria guidelines to make medical necessity decisions on a case-by-case basis, based on the information provided on the member's health status.

For the following Gene Expression Profiling for Cancer Indications HCPCS Code, 81518, Humana Healthy Horizons™ in Ohio uses the below coverage determination criteria.

Providers may submit authorization request(s) through the provider portal.

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 also 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 OHMCDUM@humana.com.

Description:

Gene Expression Profiling for Cancer Indications HCPCS Code(s)	
HCPCS Code(s) **Summary**	81518 * Other Genetic codes may be found in other policies
HCPCS Code(s)	**Description**
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

Gene expression profiling (GEP) is a laboratory test that measures the activity, or expression, of ribonucleic acid (RNA) of hundreds to thousands of genes at one time to give an overall picture of gene activity. GEP tests are typically performed on tumor tissue but may also be performed on other specimens such as blood. These tests often use microarray technology though other methodologies, such as next generation sequencing (NGS), whole transcriptome sequencing and reverse transcription polymerase chain reaction (RT-PCR), are also used.

GEP tests are currently offered primarily for the management of cancer, most notably breast. GEP is offered to estimate risk of recurrence metastasis) and predict likelihood of benefit from chemotherapy or extended use of endocrine (hormone) therapy for an individual diagnosed with early-stage invasive node negative (no cancer cells detected in lymph glands) or node positive (cancer cells detected in lymph glands) breast cancer. Breast Cancer Index (BCI) is an example of this type of test.

GEP tests differ from germline genetic tests. GEP tests analyze RNA which is dynamic, responds to cellular environmental signals, are not usually representative of an individual's germline DNA and are not inheritable. Germline genetic testing analyzes an individual's deoxyribonucleic acid (DNA) to detect genetic variants (mutations). Germline mutations are inherited, are constant throughout an individual's lifetime and are identical in every cell of the body.

Procedures:

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:
   - 3.1 Federal or state regulation, including medical criteria published in the Ohio Administrative Code, Chapter 5160.
   - 3.2 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).
   - 3.3 Humana Healthy Horizons™ in Ohio clinical policies
   - 3.4 In the case of no guidance from above, additional information that the clinical reviewer will consider, when available, includes;
     - 3.4.1 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;
     - 3.4.2 Professional standards for safety and effectiveness recognized in the US for diagnosis, care, or treatment;
     - 3.4.3 Medical association publications;
     - 3.4.4 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.;
     - 3.4.5 Published expert opinions;
     - 3.4.6 Opinion of health professionals in the area of specialty involved;
     - 3.4.7 Opinion of attending provider;
   - 3.5 Dental: DentaQuest coverage guidelines and policies
     Dental Coverage - Humana Healthy Horizons in Ohio | Humana
   - 3.6 Vision: EyeMed coverage guidelines and policies
     Vision Care - Humana Healthy Horizons - Ohio Medicaid | Humana
4. 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 medical necessity determination.

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,” and “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.

Coverage Determination Criteria:

Any mandates from the State of Ohio for gene expression profiling take precedence over this medical coverage policy. Humana members may be eligible under the Plan for Breast Cancer Index (BCI) (81518) for an individual diagnosed with breast cancer for the following indications:

- To assess necessity of adjuvant chemotherapy or adjuvant endocrine therapy; AND
  - Breast tumor is HER2 negative*; AND
  - Breast tumor is hormone receptor (HR) positive; AND
  - Breast tumor size greater than 0.5 cm; AND
  - Medically eligible for adjuvant therapy; AND
  - Negative axillary lymph nodes (nonmetastatic) (pN0), axillary-node micrometastasis (pN1mi) no greater than 2.0 mm or metastases in 1-3 lymph nodes (pN1); OR
- To guide decisions about extended endocrine therapy when the individual to be tested meets the above criteria and has received 5 years of endocrine therapy without recurrence.

Multiple Primary Breast Tumors Humana Healthy Horizons™ in Ohio members may be eligible under the Plan for GEP for multiple primary breast tumors performed with any of the following:

• Breast Cancer Index (BCI)

- AND the following criteria are met:
  - Each primary breast tumor must meet the criteria above; AND
  - Test result from 1 tumor must be known before testing a subsequent tumor; AND
  - Test result from the first tumor indicates a risk classification of low or intermediate.
- HER2 status determined by fluorescence in situ hybridization (FISH), immunohistochemistry (IHC) or in situ hybridization (ISH) assay.

Coverage Limitations:

Humana Healthy Horizons™ in Ohio members may NOT be eligible under the Plan for GEP for any cancer indications other than those listed above including, but may not be limited to:

- Breast cancer including, but may not be limited to:
  - Determination of ER, PR and HER2 status
  - Evaluation of HER2 positive or triple negative breast cancer
  - Evaluation of tumors less than or equal to 0.5 cm
  - Multiple primary breast tumors if the GEP breast cancer test result on first tumor indicates high risk.

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.

Background:

Additional information about cancer may be found from the following websites:

• American Cancer Society

• National Comprehensive Cancer Network

• National Library of Medicine

Definitions:

1. Adverse Benefit Determination – As defined in OAC rule 5160-26-01, is a managed care entity's (MCEs):
    (1) 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.
    (2) Reduction, suspension, or termination or services prior to the member receiving the services previously authorized by the MCE;
    (3) Failure to provide services in a timely manner as specified in rule 5160-26-03.1 of the Administrative Code;
    (4) Failure to act within the resolution timeframes specified in rule 5160-26-08.4 of the Administrative Code;
    (5) 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
    (6) 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 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 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.

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Version Control:

11/28/2023 - Code 81518 from Humana Healthy Horizons™ in Ohio policy H1238 was placed into this new policy (H1379) and coverage criteria was written for determining medical necessity. - M. Joyce Medicaid Clinical Delivery Experience.