Gene Expression Profiling for Noncancer Indications

Humana

Medical Coverage Policy

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Change Summary: Updated Description, Coverage Determination, Provider Claims Codes, References

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Disclaimer

Description

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 has been proposed for indications beyond the cancer space including longevity prediction, pain management, psychiatric conditions, psoriasis

and pulmonary diseases. Noncancer indications for GEP include, but may not be limited to:

- **Congenital epigenetic disorders** – Evaluation of methylation patterns associated with single-gene disorders purported to screen an individual with developmental delay suggestive of an epigenetic disorder (**EpiSign Complete**).

- **Longevity** – Proposed as a method to predict duration of an individual's life. **MindX Longevity** is an example of this type of test.

- **Pain** – Suggested to determine appropriate medication for pain relief tailored to the individual. An example is **MindX Pain**.

- **Psoriasis** – Under investigation and performed by mRNA and NGS via skin-surface collection using an adhesive patch to predict the likelihood of response to psoriasis biologics (**Mind.Px**).

- **Psychiatric conditions** – Proposed to assess risk of mental health disorders such as mood disorders (depression/bipolar), post-traumatic stress disorder (PTSD) and risk of suicide. Also purported to establish a diagnosis and assist with treatment decisions personalized to the individual. Examples include **MindX Mood, MindX Stress, MindX Suicidality and MindXOne Blood Test – Anxiety.**

- **Pulmonary diseases** – Suggested to aid in the differentiation of idiopathic pulmonary fibrosis and other interstitial lung diseases (**Envisia Genomic Classifier**).

- **Systemic lupus erythematosus** – Proposed for the management of systemic lupus erythematosus. An example of this type of test is **LuGene**.

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.

Test/Indication	Medical Coverage Policy
GEP for cancer such as breast	Gene Expression Profiling for Cancer Indications
GEP for prostate cancer	Gene Expression Profiling for Prostate Cancer

Coverage Determination

Any state mandates for GEP for noncancer indications take precedence over this medical coverage policy.

Humana members may **NOT** be eligible under the Plan for **GEP for any noncancer indications** including, but may not be limited to:

- Congenital epigenetic disorder including, but may not be limited to, EpiSign Complete (0318U)
- Longevity prediction including, but may not be limited to, MindX Blood Test Longevity (0294U)
- Pain including, but may not be limited to, MindX Blood Test Pain (0290U)
- Psoriasis including, but may not be limited to, Mind.Px (0258U)
- Psychiatric conditions including, but may not be limited to:
  - MindX Blood Test Mood (0291U)
  - MindX Blood Test Stress (0292U)
  - MindX Blood Test Suicidality (0293U)
  - MindXOne Blood Test – Anxiety (0437U)
- Pulmonary disease (idiopathic pulmonary fibrosis, interstitial lung diseases) including, but may not be limited to, Envisia Genomic Classifier (81554)
- Systemic lupus erythematosus including, but may not be limited to, LuGene

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

Background

Additional information about **behavioral health, congenital epigenetic disorder, pain, psoriasis or pulmonary diseases** may be found from the following websites:

- American Academy of Dermatology
- American Academy of Pain Medicine
- American Lung Association
- American Psychiatric Association
- National Library of Medicine

Medical Alternatives

Alternatives to **GEP for behavioral health** include, but may not be limited to:

- Clinical interviews and examinations

Alternatives to **GEP for idiopathic pulmonary fibrosis and other interstitial lung diseases** include, but may not be limited to:

- Chest high resolution computed tomography (HRCT)
- Histopathologic analysis

Alternatives to **GEP for pain or psoriasis** include, but may not be limited to:

- Physical examination

Physician consultation is advised to make an informed decision based on an individual's health needs.

Humana may offer a disease management program for this condition. **The member may call the number on his/her identification card to ask about our programs to help manage his/her care.**

Provider Claims Codes

Any CPT, HCPCS or ICD codes listed on this medical coverage 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
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])	**Not Covered**
0258U	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics	**Not Covered**
0290U	Pain management, mRNA, gene expression profiling by RNA sequencing of 36 genes, whole blood, algorithm reported as predictive risk score	**Not Covered**
0291U	Psychiatry (mood disorders), mRNA, gene expression profiling by RNA sequencing of 144 genes, whole blood, algorithm reported as predictive risk score	**Not Covered**
0292U	Psychiatry (stress disorders), mRNA, gene expression profiling by RNA sequencing of 72 genes, whole blood, algorithm reported as predictive risk score	**Not Covered**
0293U	Psychiatry (suicidal ideation), mRNA, gene expression profiling by RNA sequencing of 54 genes, whole blood, algorithm reported as predictive risk score	**Not Covered**
0294U	Longevity and mortality risk, mRNA, gene expression profiling by RNA sequencing of 18 genes, whole blood, algorithm reported as predictive risk score	**Not Covered**
0318U	Pediatrics (congenital epigenetic disorders), whole genome methylation analysis by microarray for 50 or more genes, blood	**Not Covered**

0437U	Psychiatry (anxiety disorders), mRNA, gene expression profiling by RNA sequencing of 15 biomarkers, whole blood, algorithm reported as predictive risk score	**Not Covered** **New Code Effective 01/01/2024**
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

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