Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP321

Section: Medical Benefit Policy

Subject: Gene Expression Profiling for Cutaneous Melanoma

I. Policy: Gene Expression Profiling for Cutaneous Melanoma

II. Purpose/Objective:

To provide a policy of coverage regarding Gene Expression Profiling for Cutaneous Melanoma

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Melanoma is an aggressive cancer that can be difficult to diagnose. Improved patient outcomes is attributed to accurate and early diagnosis of melanocytic lesions. Histopathologic examination is adequate for most cases, however, approximately 15% of lesions are diagnostically challenging to diagnose by histopathology. In equivocal cases, members are at risk of receiving indeterminate or inaccurate diagnoses, leading to inappropriate treatment. Gene expression profiling is thought to provide additional clarity in these difficult to diagnose cases.

INDICATIONS:

COMMERCIAL AND MEDICARE BUSINESS SEGMENT:

Gene expression profiling for cutaneous melanoma utilizing the myPath Melanoma is considered medically necessary when the following criteria are met:

- The lesion is considered to be a non-metastatic, melanocytic lesion that has not been previously treated, and
- Histopathology and clinical characteristics have not clearly differentiated the lesion as being benign or malignant, and
- The results of the gene expression testing will be used in conjunction with the clinical evaluation, histopathological features and other diagnostic procedures to determine and/or alter the treatment plan

COMMERCIAL AND MEDICARE BUSINESS SEGMENT:

Gene expression profiling for cutaneous melanoma utilizing the DecisionDx-Melanoma test is considered medically necessary when the following criteria are met:

- Patients diagnosed with pathologic stage sentinel lymph node biopsy (SLNB) eligible T1b and T1a cutaneous melanoma tumors with clinically negative sentinel node basins who are being considered for SLNB to determine eligibility for adjuvant therapy. (Per current NCCN and ASCO guidelines, SLNB eligible patients are defined as:
    - Patients with T1a tumors:
        - in whom there is significant uncertainty about the adequacy of microstaging (positive deep margin), or
        - with Breslow depth <0.8 mm and with other adverse features (eg. very high mitotic index [≥2/mm2], lymphovascular invasion, or a combination of these factors)
    - Patients with T1b tumors (≥0.8 mm or < 0.8 mm with ulceration)
    - Patients with T2 tumors

COMMERCIAL AND MEDICARE BUSINESS SEGMENT:

Gene expression profiling for cutaneous melanoma utilizing the Pigmented Lesion Assay RNA gene expression test on skin samples obtained via adhesive patches is considered medically necessary when the following criteria are met:.

- The lesion must meet one or more ABCDE criteria (Asymmetry, Border, Color, Diameter, Evolving)*
- Primary melanocytic skin lesions is between 5mm and 19mm
- Lesion skin is intact (i.e. non-ulcerated or non-bleeding lesions)
- Lesion does not contain a scar or has been previously biopsied
- Lesion is not located in areas of psoriasis, eczema or similar skin conditions
- Lesion has not already been diagnosed as melanoma or for which the clinical suspicion is sufficiently high that the treating clinician believes melanoma is a more likely diagnosis than not
- Lesion is located in areas other than palms of hands, soles of feet, nails, mucous membranes and hair covered areas that cannot be trimmed.

*ABCDE criteria:
Asymmetry - The shape of one half does not match the other half.
Border that is irregular - The edges are often ragged, notched, or blurred in outline. The pigment may spread into the surrounding skin.
Color that is uneven - Shades of black, brown, and tan may be present. Areas of white, gray, red, pink, or blue may also be seen.
Diameter - There is a change in size, usually an increase. Melanomas can be tiny, but most are larger than 6 millimeters wide (about 1/4 inch wide).
Evolving - The mole has changed over the past few weeks or months.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Gene expression profiling for cutaneous melanoma

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws

regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

81479 – Unlisted Molecular Pathology Procedure
81529 - ONCOLOGY (CUTANEOUS MELANOMA), MRNA, GENE EXPRESSION PROFILING BY REAL-TIME RT-PCR OF 31 GENES (28 CONTENT AND 3 HOUSEKEEPING), UTILIZING FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE, ALGORITHM REPORTED AS RECURRENCE RISK, INCLUDING LIKELIHOOD OF SENTINEL LYMPH NODE METASTASIS
81599 – Unlisted multianalyte assay with algorithmic analysis [when specified as uveal or cutaneous melanoma gene expression tests, such as DecisionDx-Melanoma, myPath Melanoma]
0089U - Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es) [DermTech Pigmented Lesion Assay]
0090U Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, malignant) use for MyPathMelanoma

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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National Comprehensive Cancer Network (NCCN) – Melanoma v2.2021

Hayes Genetic Testing Evaluation (GTE) Synopsis: DecisionDx- Melanoma

MolDX: DecisionDx-Melanoma (DL37725)

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Local Coverage Determination (LCD):MolDX: Melanoma Risk Stratification Molecular Testing (L37750)

MOLDX: Pigmented Lesion Assay (L38051)

MolDX: myPath® Melanoma Assay (L37859)

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This policy will be revised as necessary and reviewed no less than annually.

Devised: 4/18

Revised: 11/18 (expand Medicare coverage); 5/19 (expand commercial and Medicare coverage); 10/20 (add PLA testing)

Reviewed: 5/20; 10/21

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies