Local Coverage Article:
MolDX: TP53 Gene Test Billing and Coding Guidelines (A55487)

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**Contractor Information**

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**Article Information**

**General Information**

**Article ID**
A55487

**Original Article Effective Date**
05/22/2017

**Article Title**
MolDX: TP53 Gene Test Billing and Coding Guidelines

**Revision Effective Date**
11/29/2017

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**Revision Ending Date**
N/A

**Retirement Date**
N/A
Article Guidance

Article Text:

TP53 gene testing may be performed during the diagnosis of Li-Fraumeni syndrome (LFS), a cancer predisposition syndrome associated with the development of specific tumors. Since clinical symptoms and diagnosis usually occur prior to Medicare eligibility and carrier testing is not a covered benefit, the MolDX Team has determined TP53 gene tests are a statutorily excluded service.

To receive a TP53 gene sequencing service denial, please submit the following claim information:

- Appropriate CPT code according to exons tested
  - Code 81404 – TP53, targeted sequence analysis of 2-5 exons
  - Code 81405 – TP53, full gene sequence or targeted analysis of greater than 5 exons

- An Advance Beneficiary Notice (ABN) is not required for statutorily excluded services.
  - For a voluntary issued ABN, append with GX modifier
  - To indicate a known statutorily excluded service, append with a GY modifier

- Select the appropriate diagnosis for the patient

- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part B claim field/types:
  - Loop 2400 or SV101-7 for the 5010A1 837P
  - Item 19 for paper claim

- Enter DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:
  - Line SV202-7 for 837I electronic claim
  - Block 80 for the UB04 claim form

Reference: Sec. 1862 (1)(A) Statutory Exclusion covers diagnostic testing “except for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,...”
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

**Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

**CPT/HCPCS Codes**  
**Group 1 Paragraph:** N/A

**Group 1 Codes:**  
**Group 1 CPT/HCPCS Code**  
81404  
MOLECULAR PATHOLOGY PROCEDURE, LEVEL 5 (EG, ANALYSIS OF 2-5 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 6-10 EXONS, OR CHARACTERIZATION OF A DYNAMIC MUTATION DISORDER/TRIPLET REPEAT BY SOUTHERN BLOT ANALYSIS)

81405  
MOLECULAR PATHOLOGY PROCEDURE, LEVEL 6 (EG, ANALYSIS OF 6-10 EXONS BY DNA SEQUENCE ANALYSIS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 11-25 EXONS, REGIONALLY TARGETED CYTOGENOMIC ARRAY ANALYSIS)

**ICD-10 Codes that are Covered** N/A

**ICD-10 Codes that are Not Covered** N/A

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**Revision History Information**

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<td>11/29/2017</td>
<td>R1</td>
<td>The descriptor for 81405 was changed. Deleted the following text, &quot;MoIDX will also deny panels of tests that include the TP53 gene.&quot;</td>
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**Related Local Coverage Document(s)** N/A

**Statutory Requirements URL(s)** N/A

**Rules and Regulations URL(s)** N/A

**CMS Manual Explanations URL(s)** N/A

**Other URL(s)** N/A

**Public Version(s)** Updated on 01/23/2018 with effective dates 11/29/2017 - N/A  Updated on 03/31/2017 with effective dates 05/22/2017 - N/A

Printed on 2/2/2018. Page 3 of 4
Keywords

- TP53
- Gene
- 81404
- 81405
- Li-Fraumeni syndrome
- LFS

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