Comprehensive Genomic Profiling and Genetic Testing for Solid Tumors

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Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

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Disclaimer
The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member’s coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

Genetic Testing
Liquid Biopsy
Pharmacogenomics and Companion Diagnostics

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.
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| Lab: Special Histochemical Stains and Immunohistochemical Stains | | L35922 |
Comprehensive Genomic Profiling (CGP) (also referred to as comprehensive molecular profiling) is a type of somatic (tumor) test that involves a combination of laboratory methodologies to detect genetic alterations and the simultaneous evaluation of large numbers (hundreds to thousands) of biomarkers in tumor tissue to aid in the management of advanced solid tumors, including guiding treatment decisions as well as determination of clinical trial eligibility. Techniques can vary from test to test and may include next-generation sequencing (NGS), fluorescence in situ hybridization (FISH) and immunohistochemistry (IHC) and often provides information on tumor mutational burden (TMB), microsatellite instability (MSI) and homologous recombination deficiency (HRD). Examples include Altera Tumor Genomic Profiling, Guardant360, NeoGenomics Solid Tumor NGS Fusion Panel and TissueNext.

Some CGP tests analyze both deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). NeoTYPE DNA & RNA – Lung is an NGS profiling test that detects single nucleotide variants, insertions/deletions, copy number variants, and/or RNA fusions in a total of 50 genes (44 genes analyzed by DNA and 19 by RNA), plus MSI and TMB. Tempus xT is another example of a CGP somatic test performed for the management of advanced cancer. Previously Tempus xT conducted sequencing for both ribonucleic acid (RNA) and deoxyribonucleic acid (DNA) within a single panel. However, a new test, Tempus xR, is now available as an independent assay dedicated solely to RNA sequencing. This means that Tempus xT focuses on DNA analysis while Tempus xR specializes in RNA analysis, and they are no longer combined into one test.

Single gene testing can be utilized to diagnose and monitor cancer including, but may not be limited to, cholangiocarcinoma, gallbladder cancer, gastrointestinal stromal tumor, glioblastoma, melanoma and thyroid cancer. This type of testing is indicated for an individual who exhibits disease symptoms and may be necessary to diagnose or rule out suspected cancer.
DNA Specimen Provenance Assignment (DSPA) Testing (eg, know error System) is a molecular diagnostic test intended for the protection and control of tissue samples to purportedly decrease the incidence of diagnostic mistakes due to the misidentification, specimen transposition or cell contamination of samples, also known as specimen provenance complications (SPCs). Breast and prostate tissues are most often tested but other tissue types, such as bone marrow, may also be examined.

**Coverage Determination**

*iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.*

Genetic tests must demonstrate clinical utility, analytical and clinical validity and fulfill the CMS “reasonable and necessary” criteria. Analytic validity (test accurately identifies the gene variant), clinical validity (test identifies or predicts the clinically defined disorder) and clinical utility (test measurably improves clinical outcomes) of the genetic test is supported by generally accepted standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, specialty society recommendations, and views of physicians practicing in relevant clinical areas. The test must be ordered by a physician who is treating the beneficiary and the results will be used in the management of a beneficiary’s specific medical problem.

*For jurisdictions with no Medicare guidance for a particular test, *iCare* will utilize the MolDX program and Technical Assessments for molecular assays as the standard to evaluate clinical utility, analytical and clinical validity in conjunction with adhering to Medicare’s reasonable and necessary requirement.*

*In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, *iCare* may consider the following criteria:*  

**Comprehensive Genomic Profiling for Solid Tumors**

*Comprehensive genomic profiling (CGP) for solid tumors* will be considered medically reasonable and necessary when the following requirements are met:

- Analytic validity, clinical validity and clinical utility of the genetic test is supported by the MolDX program; AND

- The test is ordered by a treating physician; AND

- **ALL** of the following:
  - Cancer that has returned (recurrent or relapsed), cancer that does not respond to treatment (refractory), cancer that has spread from original site to another part of the body (metastatic) or advanced stages III or IV cancer; **AND**
Individual has not been previously tested using the same comprehensive genomic profiling test for the same primary diagnosis; AND

Decision to seek further cancer treatment (eg, therapeutic chemotherapy)

Criteria for Single Gene Testing

*IDH1 (81120) and/or IDH2 (81121) gene analysis* will be considered medically reasonable and necessary for the following indications:

- Cholangiocarcinoma that is locally advanced, metastatic or unresectable disease (*IDH1 only*);\textsuperscript{71} OR
- Gallbladder cancer that is metastatic or unresectable disease (*IDH1 only*);\textsuperscript{71} OR
- Glioblastoma\textsuperscript{15}

*KIT (c-KIT) gene analysis* will be considered medically reasonable and necessary to guide therapeutic decision making\textsuperscript{43} when for the following indications:

- Gastrointestinal stromal tumor (GIST) (81272);\textsuperscript{15} OR
- Melanoma, metastatic or unresectable (81272)\textsuperscript{15}

*MGMT promoter methylation testing* (81287) will be considered medically reasonable and necessary to guide therapeutic decision making\textsuperscript{43} for the following indications:

- Glioblastoma;\textsuperscript{15} OR
- Neuroendocrine tumors\textsuperscript{15}

*NRAS gene analysis* (81311) will be considered medically reasonable and necessary for the following indications:

- Metastatic colorectal cancer when needed to determine if a Medicare covered therapy is a reasonable option given the individual’s specific clinical presentation;\textsuperscript{15,37,38,39,40,41} OR

- Metastatic melanoma;\textsuperscript{15} OR

- Thyroid carcinoma\textsuperscript{15}

*PDGFRA gene analysis* (81314) will be considered medically reasonable and necessary to guide therapeutic decision making\textsuperscript{43} when an individual presents with a mass known or clinically suspected to be GIST.\textsuperscript{13}

*TERT gene analysis* (81345) will be considered medically reasonable and necessary for glioblastoma.\textsuperscript{13,15}
The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following tests may not be considered a benefit (statutory exclusion):

- Tests performed to measure the quality of a process, including DNA Specimen Provenance Assignment (DSPA) testing to decrease specimen provenance complications (SPC) (eg, know error System) (81265)\(^7,8,9,10,11,12\)
- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law;\(^8\) OR
- Tests that confirm a diagnosis or known information;\(^8\) OR
- Tests to determine risk for developing a disease or condition;\(^8\) OR
- Tests performed to measure the quality of a process;\(^8\) OR
- Tests without diagnosis specific indications;\(^8\) OR
- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial\(^8\)

These treatments and services fall within the Medicare program’s statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services/items fall within the Medicare program’s statutory exclusion at 1862(a)(12), which prohibits payment.

The following items will not be considered medically reasonable and necessary:

- Genetic tests that have not demonstrated clinical utility, analytical and clinical validity via the MolDX Program
- \(TERT\) mutation testing for melanoma
A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following items will not be considered medically reasonable and necessary:

- CGP RNA sequencing as a stand-alone test without MolDX approval (eg, Tempus xR)

A review of the current medical literature shows that there is no evidence to determine that this service is standard medical treatment. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

**Summary of Evidence**

**Tempus xR**

Tempus xR is now offered as a stand-alone test, separate from Tempus xT. In the past, Tempus xT sequenced both RNA and DNA in a single panel but now Tempus xR focuses solely on RNA and Tempus xT is dedicated to DNA analysis. Most CGP tests typically analyze both DNA and RNA in a single panel and there is insufficient evidence for RNA-only CGP. The validity of analysis, its clinical relevance and utility are yet to be established in published, peer-reviewed medical literature.

**TERT Mutation Testing for Melanoma**

A systematic review and meta-analysis investigation the connection between somatic mutations in the TERT gene promoter and melanoma survival revealed limited yet suggestive evidence of an adverse impact of TERT mutations on the survival of an individual diagnosed with melanoma. The authors gathered data from 19 independent studies and found that individuals with TERT-mutated melanoma had a significantly worse overall survival compared to wild-type mutations.58

**Coding Information**

Any codes listed on this 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.

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<td>81120</td>
<td>IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)</td>
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<td>81121</td>
<td>IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)</td>
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<td>81265</td>
<td>Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)</td>
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<td>81272</td>
<td>KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18)</td>
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<td>MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme) promoter methylation analysis</td>
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<td>81311</td>
<td>NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)</td>
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<td>PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18)</td>
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<td>TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)</td>
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<td>Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)</td>
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<td>Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations</td>
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