Independence

Medical Policy Bulletin

Title:

eviCore Lab Management Program (Independence)

Policy #:

06.02.52r

This policy is applicable to the Company's commercial products only. Policies that are applicable to the Company's Medicare Advantage products are accessible via a separate Medicare Advantage policy database.

The Company makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Medical Policy Bulletin document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. This Medical Policy Bulletin will be reviewed regularly and be updated as scientific and medical literature becomes available. For more information on how Medical Policy Bulletins are developed, go to the Policy Types and Descriptions section of this Medical Policy Web site.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's contract.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

This policy does not apply to those members for whom Independence Administrators serve as the claims administrator.

The intent of this policy is to communicate that the Company has delegated the responsibility for utilization management activities of genetic/genomic tests and certain molecular analyses and cytogenetic tests to CareCore National, LLC d/b/a eviCore healthcare (eviCore), with the exception of services performed in the emergency room or during an inpatient or observation unit stay.

PRE-SERVICE REVIEWS

The Company requires pre-service reviews for certain genetic/genomic tests through CareCore National, LLC d/b/a eviCore healthcare (eviCore), including but not limited to:

- BRCA gene testing (breast and ovarian cancer syndrome)
- Lynch syndrome gene testing
- Cystic fibrosis full gene sequencing and deletion/duplication analyses
- Select pharmacogenomic testing

- Genetic Panels (e.g., cancer type panels for colon, breast, or neuroendocrine cancers)
- Cancer gene expression tests (e.g., OncotypeDX®, MammaPrint®, Afirma® Thyroid Fine-Needle Aspiration [FNA] Analysis)
- Tumor molecular profiling (e.g., FoundationOne®, neoTYPE™, OncoPlexDX®)
- Expanded carrier screening panels (e.g., Carrier Status DNA Insight®, Counsyl Family Prep Screen, Pan-Ethnic Carrier Screening)
- Genome-wide tests (e.g., Microarray studies, Whole exome testing, Whole genome testing, Mitochondrial genome or nuclear testing)

Refer to Attachment A of this policy for a complete list of procedure codes that represent genetic/genomic tests requiring pre-service reviews. In addition to the requirement for pre-service reviews, the procedure codes listed in Attachment A will undergo prepayment reviews.

Genetic/genomic tests, which are listed in Attachment A of this policy, that do not meet coverage criteria may be considered experimental/investigational or not medically necessary, and, therefore, not covered.

PREPAYMENT REVIEWS

All genetic/genomic tests, along with certain molecular analyses (e.g., immunohistochemistry [IHC], morphometric analyses, flow cytometry) and molecular cytogenetic tests (e.g., fluorescent in situ hybridization [FISH], karyotyping)**,** will be reviewed prior to claim payment through CareCore National, LLC d/b/a eviCore healthcare (eviCore).

In addition to the procedure codes in Attachment A, refer to Attachment B of this policy for a list of additional procedure codes that represent laboratory tests that will undergo prepayment reviews. The procedure codes listed in Attachment B do not require pre-service reviews.

Genetic/genomic tests, molecular analyses, and cytogenetic tests, which are listed in Attachment B of this policy, that do not meet coverage criteria may be considered experimental/investigational or not medically necessary, and, therefore, not covered.

EVICORE LAB MANAGEMENT PROGRAM CLINICAL GUIDELINES

eviCore utilizes its Lab Management Program Clinical Guidelines for medical necessity determination related to the delegated genetic/genomic tests and certain molecular analyses and cytogenetic tests.

eviCore's Lab Management Program Clinical Guidelines are available at: https://www.evicore.com/healthplan/IBC.

REQUIRED DOCUMENTATION

The individual’s medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider’s office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the service.

Guidelines

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, genetic/genomic tests, molecular analyses, and cytogenetic tests are covered under the medical benefits of the Company’s products when the medical necessity criteria for the services are met. However, services that are identified as experimental/investigational or not medically necessary are not eligible for coverage or

reimbursement by the company.

Procedure codes listed in this policy also continue to be subject to Company claims adjudication logic, eligibility, benefits, limitations, exclusions, referral requirements, provider contracts, and Company policies.

Description

The Company has delegated utilization management of genetic/genomic testing and certain molecular analyses and cytogenetic tests to CareCore National, LLC d/b/a eviCore healthcare (eviCore). This utilization management program through eviCore will encompass pre-service reviews and/or prepayment reviews as follows:

- Pre-service reviews will be required for certain genetic/genomic tests.
- All genetic/genomic tests, along with certain molecular analyses and cytogenetic tests, will be reviewed prior to claim payment.

eviCore utilizes its Lab Management Program Clinical Guidelines for medical necessity determinations related to the delegated genetic/genomic tests and certain molecular analyses and cytogenetic tests.

eviCore's Lab Management Program Clinical Guidelines are based on peer-reviewed literature, evidence-based guidelines and recommendations from national and international medical societies, and evidence-based medical research centers, including, but not limited to, the National Comprehensive Cancer Network (NCCN), the American College of Obstetrics and Gynecologists (ACOG), the American College of Medical Genetics (ACMG), the American Society of Human Genetics (ASHG), the European Federation of Neurological Societies (EFNS), the American Academy of Neurology (AAN), the National Society of Genetic Counselors (NSGC), the Society for Assisted Reproductive Technology (SART), the American Society for Reproductive Medicine (ASRM), the American Thoracic Society (ATS), the European Respiratory Society (ERS), and the American Society of Clinical Oncology (ASCO).

References

CareCore National, LLC d/b/a eviCore healthcare. Clinical Guidelines: Lab Management Program. Available at: https://www.evicore.com/healthplan/IBC. Accessed May 7, 2020.

Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)

See Attachments A and B

ICD - 10 Procedure Code Number(s)

N/A

ICD - 10 Diagnosis Code Number(s)

N/A

HCPCS Level II Code Number(s)

See Attachments A and B

Revenue Code Number(s)

N/A

Cross Reference

Attachment A: eviCore Lab Management Program (Independence)
Description: Procedure Codes Requiring Pre-service and Prepayment Reviews
Attachment B: eviCore Lab Management Program (Independence)
Description: Procedure Codes Requiring Prepayment Reviews

Policy History

REVISIONS FROM 06.02.52r:

10/01/2020	This version of the policy became effective on 10/01/2020. Effective 10/01/2020, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing precertification and prepayment reviews through the vendor): 0016M, 0203U, 0204U, 0205U, 0208U, 0209U, 0211U, 0212U, 0213U, 0214U, 0215U, 0216U, 0217U, 0218U, 0219U, 0220U Effective 10/01/2020 the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 0221U & 022U

REVISIONS FROM 06.02.52q:

07/01/2020	This version of the policy will become effective on 07/01/2020. Effective 07/01/2020, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing pre-service and prepayment reviews through the vendor): 0172U, 0173U, 0175U, & 0179U Effective 07/01/2020, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 0177U, 0180U, 0181U, 0182U, 0183U, 0184U, 0185U, 0186U, 0187U, 0188U, 0189U, 0190U, 0191U, 0192U, 0193U, 0194U, 0195U, 0196U, 0197U, 1098U, 0199U, 0200U, 0201U -- Procedure code 0068U has a revision to the name of the laboratory/manufacturer for the testing, but not the actual code narrative/descriptor.

On July 01st, 2020, the following updates will be made to the eviCore Lab Management Clinical Guidelines. These guidelines will be used by eviCore during the utilization management reviews' (i.e. medical necessity and/or prepayment reviews) processes starting on July 01st, 2020. The updated guidelines are accessible via a link contained in the Policy section of this medical policy bulletin.

07/01/2020 Guideline Updates for eviCore Lab Management Program (Policy #: 06.02.52q)

Executive Summary of Changes

There are four new guidelines. 40 existing guidelines have been revised (including 13 with substantive criteria changes). Five guideline were retired. See the below tables for details.

Below is a summary of the guideline changes

New Guidelines:

1. Date of Service and Authorization Period Effective Date
2. CHARGE Syndrome Genetic Testing
3. GeneSight Psychotropic Test
4. myChoice CDx

Retired Guidelines:

1. AssureMDx Testing for Bladder Cancer
2. Mylema Prognostic Risk Signature (MyPRS)
3. RosettaGX Reveal
4. Corus CAD for Obstructive Coronary Artery Disease
5. Phamacogenomic Testing Panels for Major Depressive Disorders

Criteria Updates (Substantive):

1. Investigational and Experimental Molecular/Genomic
2. Pharmacogenomic Testing for Drug Toxicity and Response
3. Afirma Thyroid Cancer Classifier Tests
4. Chromosome Analysis for Blood, Bone Marrow, and Solid Tumor Cancers
5. Familial Hypercholesterolemia Genetic Testing
6. Gaucher Disease Testing
7. HLA.B*1502 Variant Analysis for Carbamazepine Response
8. Immunohistochemistry (IHC)
9. UroVysion FISH for Bladder Cancer
10. Non-Invasive Prenatal Testing
11. Molecular Gastrointestinal Pathogen Panel (GIPP) Testing
12. CYP2C9 and VKORC1 Testing for Warfarin Response
13. Genitourinary Conditions Molecular Testing

Criteria Updates (Non-Substantive):

1. ABL Tyrosine Kinase Sequencing for Chronic Myeloid Leukemia
2. Alpha-1-Antitrypsin Deficiency Testing
3. BRCA Analysis
4. Breast Cancer Index for Breast Cancer Prognosis
5. Chromosome Analysis
6. Cystic Fibrosis Testing
7. DPYD Variant Analysis for 5-FU Toxicity
8. EndoPredict for Breast Cancer Prognosis

	9. Familial Adenomatous Polyposis Testing 10. Hereditary (Germline) Testing After Tumor (Somatic) Testing 11. Leber Hereditary Optic Neuropathy (LHON) Genetic Testing 12. Legius Syndrome Genetic Testing 13. Li-Fraumeni Syndrome Testing 14. Lynch Syndrome Genetic Testing 15. Mammaprint 70.Gene Breast Cancer Recurrence Assay 16. Mitochondrial DNA Deletion Syndromes 17. Mitochondrial Encephalomyopathy, Lactic Acidosis, and Stroke-like Episodes (MELAS) Genetic 18. Mitochondrial Genetic Testing 19. Mitochondrial Neurogastrointestinal Encephalopathy (MNGIE) 20. Myoclonic Epilepsy with Ragged Red Fibers (MERRF) 21. Neurofibromatosis Type 1 Genetic Testing 22. Neurogenic Muscle Weakness, Ataxia, and Retinitis Pigmentosa (NARP) 23. OncotypeDX for Breast Cancer Prognosis 24. Prosigna Breast Cancer Prognostic Gene Signature Assay 25. Somatic Mutation Testing-Solid Tumors 26. Whole Exome Sequencing 27. FoundationOne CDx ***Other Note:***(I/E = investigational & experimental) -- **See the tables below that follow (which provide more details for the guideline changes):**

New Guidelines:

Guideline Name	Guideline #	Procedure Code Impacted	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change	What is the expected impact on approvals/denials?
Date of Service and Authorization Period Effective Date	MOL.AD.314.A	None specifically - administratve policy	New administrative guideline		no change
CHARGE Syndrome Genetic Testing	MOL.TS.324.A	Non-specific codes - however, currently addressed by clinical use guideline so nothing new to impact coverage	New test specific guideline. Previously addressed by clinical use guideline.		no change

GeneSight Psychotropic Test	MOL.TS.340.A	Numerous - however, currently addressed by different policy so nothing new to impact coverage	New guideline. Previous one was broad and included information for all panels for major depressive disorder. Given the increasing publications and questions from clients, the decision was made to create a GeneSight specific guideline to clarify eviCore's position.		no change
myChoice CDx	MOL.TS.341.A	Non specific code - however, currently addressed by different policy so nothing new to impact coverage	New test specific guideline. Previously addressed by clinical use guideline.		no change

Retired Guidelines:

Guideline Name	Guideline #	Procedure Code Impacted	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change	What is the expected impact on approvals/denials ?
AssureMDx Testing for Bladder Cancer	MOL.TS.205.A	Non specific procedure code	Test does not appear to be on the market anymore. Test was added to our clinical use guideline in the case that it comes back on the market, it will still be I/E.		no change
Mylema Prognostic Risk Signature (MyPRS)	MOL.TS.237.A	Non specific procedure code	Test does not appear to be on the market anymore. Test was added to our clinical use guideline in the case that it comes back on the market, it will still be I/E.		no change
RosettaGX Reveal	MOL.TS.283.A	Non specific procedure code	Test does not appear to be on the market anymore. Test was added to our clinical use guideline in the case that it comes back on the market, it will still be I/E.		no change
Corus CAD for Obstructive Coronary Artery Disease	MOL.TS.154.A	81493	Test is not on the market anymore. The lab closed down.		no change

Phamacogenomic Testing Panels for Major Depressive Disorders	MOL.TS.272.A	None- this is being replaced by a new guideline and our existing clinical use guideline that will address all codes	This version was broad and addressed more than Genesight. This created confusion among reviewers and clients. Therefore, we created a new GeneSight specific guideline and reworded our clinical use Pharmacogenomic guideline to address other panels to clarify.		no change

Criteria Updates (Substantive):

1.

Guideline Name	Guideline #	Procedure Code Impacted	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change	If evidence/society/external reviewer update, provide supporting reference(s) or information.
Investigational and Experimental Molecular/Genomic	MOL.CU.117.I	0170U added to table	Updated FDA Clearance verbiage; Added Clarifi; Added myPRS, AssureMDx, and Rosetta Reveal given that the tests do not appear to be offered anymore and we wanted to remove test-specific policies - however, given that we are not certain that the tests are gone for good, we wanted to keep them in the manual in case they come back up	evidence update from peer reviewed literature	Numerous evidence reviews for the various tests that are in the I/E policy
Pharmacogenomic Testing for Drug Toxicity and Response	MOL.CU.118.A	0169U added to table	Criteria update: Added DRD4 dopamine D4 receptor p450 into the non-covered list. Deleted KRAS for response to erlotinib for NSCLC. Also added "For somatic mutation testing in hematological malignancies, see the guideline, Somatic Mutation Testing - Hematological Malignancies."; Revamped the entire policy; clearly stated panels are I/E. Moved list of panels to this policy from I/E. Added NT (NUDT15 and TPMT) Genotyping Panel from RPRD Diagnostics (0169U)	evidence update from peer reviewed literature	Numerous evidence reviews for the various tests that are in the pharmacogenomic clinical use guideline
Afirma Thyroid Cancer Classifier Tests	MOL.TS.122.A	None	Criteria: Removed billing redirection to different code given that this code is still being used and many clients have contracts built around this code. It also allows for visibility into what test is being performed. Updated Background. Updated Test Information; Updated Guidelines and Evidence. Updated References.	content clarification/information	Edits made to ensure policy reflects billing and claims practices; updates based on professional society statements

Chromosome Analysis for Blood, Bone Marrow, and Solid Tumor Cancers	MOL.TS.151.A	None	Criteria: language clarification limiting policy to bone marrow chromosome analysis; Title change: Chromosome Analysis for Blood and Bone Marrow Cancers; Language edits throughout: focused policy on chromosome analysis of bone marrow by karyotype to reflect the medical necessity criteria: CPT code table: deleted solid tumor karyotype codes and microarray code; Test Information: deleted microarray information; References: updated; Admin edits: throughout	content clarification/information	Policy edited for clarification and focus to single sample type
Familial Hypercholesterolemia Genetic Testing	MOL.TS.169.A	None	Criteria: removed MEDPED diagnostic criteria, as this is diagnostic criteria set without a category for probable or possible FH (the medical criteria we deem necessary for testing); Background: expanded with additional information; Test information: updated gene/mutation information; G&E: updated to 2019 NICE guidance on FH. Added Canadian Cardiovascular Society position statement; References: updated	content clarification/information	Edits to criteria for clarity and efficiency of review; updates based on current professional society guidelines (NICE, Canadian Cardiovascular Society)
Gaucher Disease Testing	MOL.TS.173.A	None	Criteria: allow GBA sequencing as a first tier test; Throughout: use common mutation analysis instead of targeted mutation analysis and use glucocerebrosidase instead of glucosylceremidase as these represent more commonly used terms; CPT code table: updated name of panel test to align with AMA name; Background: language clarifications and update; Guidelines and Evidence: updated; Test Information: language update; References: updated	external review recommendation	Edits made to assure alignment with current AMA code descriptions and current clinical practice with regard to terminology and testing practices
HLA.B*1502 Variant Analysis for Carbamazepine Response	MOL.TS.186.A	None	Criteria: add coverage prior to the initiation of oxcarbazepine therapy in addition to carbamazepine therapy; Background: added into on oxcarbazepine; Guidelines and Evidence: updated CPIC guideline, added literature review on oxcarbazepine coverage, updated FDA labeling info with oxcarbazepine info; References: updated, new added	evidence update from peer reviewed literature	Edits made to align with FDA prescribing information
Immunohistochemistry (IHC)	MOL.CS.104.A	None	Criteria: increased maximum units for 88341 to 13 to align with CMS	external review recommendation	This aligns with CMS MUEs

UroVysion FISH for Bladder Cancer	MOL.CS.108.A	None	Criteria: added billing and reimbursement section to indicate that 88271 is not reimbursed for this test; Background updated; Guidelines and Evidence Added and Updated, literature review section redone; References added and Updated	content clarification/information	Labs were beginning to bill 88271 and this is not appropriate.
Non-Invasive Prenatal Testing	MOL.TS.209.A	Added 0168U to table	Criteria: edited language to clarify "prenatal" cell-free DNA. No changes to criteria; Test Information: updated terminology, clarified language RE microdeletions. Added Other considerations section to clarify that maternal serum screening should not be performed concurrently. Added Vanadis NIPT 0168U to table	content clarification/information	Reviewers were beginning to see maternal serum screening tests being sent with non invsive prenatal screening tests. These two tests should not be run concurrently; therefore, we clarified in policy.
Molecular Gastrointestinal Pathogen Panel (GIPP) Testing	MOL.CS.277.A	None	Criteria: Added 0097U into text in criteria (same as 87507 criteria), Added "Molecular GIPP testing should not be performed as test-of-cure. Therefore, it is not medically necessary to repeat testing for the same illness." Added language to clarify that only one GIPP test can be performed on the same date of service or within a week of the initial test. Updated ICD10 code table from D81.0 to D81.X.	content clarification/information	Outside subject matter expert reviewer suggested these items needed clarification in the guideline.
CYP2C9 and VKORC1 Testing for Warfarin Response	MOL.TS.156.A	None	Criteria: added other considerations section that states "CYP2C9 and VKORC1 testing for all other indications is addressed by the Pharmacogenomic Testing for Drug Toxicity and Response guideline" to direct readers to clinical use guideline for additional indications for clarification purposes.	content clarification/information	We wanted it to be clear that this guideline only addresses the warfarin use. Any other indications should be reviewed using a clinical use guideline.
Genitourinary Conditions Molecular Testing	MOL.CS.106.A	None	Criteria for 87563 M.Genitalium added	evidence update from peer reviewed literature	With the addition of a specific CPT code, we wanted to ensure appropriate coverage for this testing.

Criteria Updates (Non-Substantive)

Guideline Name	Guideline #	Procedure Code Impacted	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change	What is the expected impact on approvals/denials?

ABL Tyrosine Kinase Sequencing for Chronic Myeloid Leukemia	MOL.TS.121.A	None	Criteria: defined abbreviations for clarification purposes only. Guidelines and Evidence Updated; References Updated	content clarification/information	no change
Alpha-1-Antitrypsin Deficiency Testing	MOL.TS.124.A	None	Critera: admin edit; Admin edits; Background updated; References updated.	content clarification/information	no change
BRCA Analysis	MOL.TS.238.A	None	Criteria: updated citation numbers only; G&E: updated USPSTF guideline, added ACMG statement; References: updated	content clarification/information	no change
Breast Cancer Index for Breast Cancer Prognosis	MOL.TS.248.A	None	Criteria: changed word “sample” to “tumor” to clarify in the previous testing section. Removed "with or without knowledge of the Breast Cancer Index test" in the multiple tumor section for clarification purposes; Guidelines and Evidence: update NCCN, peer reviewed literature updated based on November 2019 evidence review; References: updated	content clarification/information	no change
Chromosome Analysis	MOL.CS.289.A	None	Criteria: wording edit but no changes to criteria; Background, Test Info, G&E: language updated and clarified; References: updated, outdated ref deleted.	content clarification/information	no change
Cystic Fibrosis Testing	MOL.TS.158.A	None	Criteria: sequencing for carrier screening: amended language for clarification: partner of individual diagnosed with CAVD was edited to partner of individual diagnosed with CFTR-related CAVD	content clarification/information	no change
DPYD Variant Analysis for 5-FU Toxicity	MOL.TS.160.A	None	Criteria: added statement that as this is germline testing it is not necessary more than once; Background: added 'gene' to section title for clarification, updated variant nomenclature, added statement that all variants thought to reduce enzyme activity are not well studied and do not have FDA-recommended dosing changes; Test information: updated variant nomenclature; References: updated	content clarification/information	no change
EndoPredict for Breast Cancer Prognosis	MOL.TS.234.A	None	Criteria: changed word “sample” to “tumor” to clarify in the previous testing section. Removed "with or without knowledge of the Endopredict test result" in the multiple testing section to clarify	content clarification/information	no change
Familial Adenomatous Polyposis Testing	MOL.TS.168.A	None	Criteria: Updated language to clarify AFAP is not a clinical diagnosis. No substantive changes.	content clarification/information	no change

Hereditary (Germline) Testing After Tumor (Somatic) Testing	MOL.CU.246.A	None	Criteria; No substantive changes, added the statement "Clinically indicated germline testing is still appropriate for patients meeting testing guidelines regardless of tumor profiling results" to exclusions andother considerations; Background: updated, typos corrected; Test Info: language clarifications; G&E: NCCN updated; References: updated	content clarification/information	no change
Leber Hereditary Optic Neuropathy (LHON) Genetic Testing	MOL.TS.192.A	None	Criteria: No substantive change, moved "no evidence of paternal transmission" higher in the criteria hierarchy, clarified previous testing req in KFM to be previous testing for familial mutation; Background: updated terminology and clinical classification, statistics, and management recommendations; Test Info: updated statistics; G&E: added International consensus statement from 2017, removed unavailable source; References: updated	content clarification/information	no change
Legius Syndrome Genetic Testing	MOL.TS.302.A	None	Criteria: minor changes in wording of KFM and SPRED1 sequencing sections for clarity, no substantive changes; Test info: Admin edits, language clarification	content clarification/information	no change
Li-Fraumeni Syndrome Testing	MOL.TS.193.A	None	Criteria: no substantove changes, separated Diagnostic testing in symptomatic individuals, Chompret Criteria, bullet # 1 into sub-bullets for clarity and ease of interpretation	content clarification/information	no change
Lynch Syndrome Genetic Testing	MOL.TS.197.A	None	Criteria: Added (see Figure A) for endometrial cancers that had previous tumor testing to clarify that genetic testing should be performed based on tumor results.	content clarification/information	no change
Mammaprint 70.Gene Breast Cancer Recurrence Assay	MOL.TS.200.A	None	Criteria: changed word “sample” to “tumor” to clarify in the previous testing section. Removed "with or without knowledge of the MammaPrint test result" in the multiple testing section to clarify; NCCN Updated.	content clarification/information	no change
Mitochondrial DNA Deletion Syndromes	MOL.TS.244.A	None	Criteria: added 'no evidence of paternal transmission' to diagnostic testing criteria, clarified language; Background and Test info: expanded with additional phenotype, mutation, and test information; G&E: updated, added Gene Review from 2019, deleted source no longer available; References: updated	content clarification/information	no change

Mitochondrial Encephalomyopathy, Lactic Acidosis, and Stroke-like Episodes (MELAS) Genetic	MOL.TS.204.A	None	Criteria: Added 'No evidence of paternal transmission' to the targeted mutation analysis section to clarify when this testing is appropriate. Updated wording of this in other sections. Background updated; Guidelines and evidence updated; References Updated	content clarification/information	no change
Mitochondrial Genetic Testing	MOL.TS.266.A	None	Criteria: Added "suggestive of a mitochondrial disorder" to clarify symptoms required. Edited word choice for paternal transmission for clarification. Updated Background; Guidelines and Evidence Updated; References Updated.	content clarification/information	no change
Mitochondrial Neurogastrointestinal Encephalopathy (MNGIE)	MOL.TS.243.A	None	Criteria: clarified previous testing wording. No substantive updates. Background updated. Guidelines and evidence updated. References Updated	content clarification/information	no change
Myoclonic Epilepsy with Ragged Red Fibers (MERRF)	MOL.TS.242.A	None	Criteria: Added "Member has not had previous whole mtDNA sequencing performed" to whole mtDNA seq section. Also updated paternal transmission language, updated language RE previous testing section of KFM criteria to make it clear that no previous testing that would detect the familial mutation could be performed. Background Updated; Guidelines and Evidence Updated; References Updated	content clarification/information	no change
Neurofibromatosis Type 1 Genetic Testing	MOL.TS.301.A	None	Criteria: non-substantive edit clarifying language for KFM testing; Background, Test Information and G&E updated; References updated and new added	content clarification/information	no change
Neurogenic Muscle Weakness, Ataxia, and Retinitis Pigmentosa (NARP)	MOL.TS.245.A	None	Criteria: Added "No evidence of paternal transmission" in targeted mutation section and reworded the statement in whole mtDNA sequencing section, In KFM section, clarified language that previous testing could not have identified the familial mutation. Background updated; Guidelines and Evidence Updated; References Updated	content clarification/information	no change
OncotypeDX for Breast Cancer Prognosis	MOL.TS.211.I	None	Criteria: changed word “sample” to “tumor” to clarify in the previous testing section. Removed "with or without knowledge of the OncotypeDX test result" in the multiple testing section to clarify	content clarification/information	no change

Prosigna Breast Cancer Prognostic Gene Signature Assay	MOL.TS.222.A	None	Criteria: changed word “sample” to “tumor” to clarify in the previous testing section. Removed "with or without knowledge of the Prosigna test result" in the multiple testing section to clarify	content clarification/information	no change
Somatic Mutation Testing-Solid Tumors	MOL.TS.230.A	None	Criteria: no substantive changes, added CPT code 81276 for KRAS mutations in metastatic colorectal cancer in 'Common cancer types and associated tumor markers' table. Added a note that states "This guideline addresses molecular markers only. It is intended to address those markers that are detected by next generation sequencing technology and those that are present on NGS panels. It does not address microsatellite instability (MSI), immunohistochemistry (IHC), or other markers that may be detected through other methods such as FISH, chromosomal microarray, routine chromosome analysis, etc."; Background: removed list of test names; G&E: update NCCN quote; References: update NCCN	content clarification/information	no change
Whole Exome Sequencing	MOL.TS.235.A	None	Criteria: removed word "whole" from whole exome sequencing to align with industry standard per expert opinion. Also changed word biochemical to laboratory to account for additional tests that would indicate inborn error of metabolism that would not be biochemical in nature. Background: Removed word "whole" from whole exome sequencing throughout the policy. References Updated. Titles Updated to Exome Sequencing.	content clarification/information	no change
FoundationOne CDx	MOL.TS.303.A	None	Criteria: Added a note that states "This guideline addresses molecular markers only. It is intended to address those markers that are detected by next generation sequencing technology and those that are present on NGS panels. It does not address microsatellite instability (MSI), immunohistochemistry (IHC), or other markers that may be detected through other methods such as FISH, chromosomal microarray, routine chromosome analysis, etc."; Guidelines and Evidence: updated NCCN; References: updated	content clarification/information	no change

REVISIONS FROM 06.02.52p:

04/01/2020	This version of the policy went through a code update process effective 04/01/2020: • Narratives for procedure codes 0154U and 0155U were revised. • Procedure codes 0169U, 0170U and 0171U were added to Attachment A of this policy. • Procedure code 0168U was added to Attachment B of this policy.

REVISIONS FROM 06.02.52o:

01/01/2020	This version of the policy will become effective on 01/01/2020. Effective 01/01/2020, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing pre-service and prepayment reviews through the vendor): 0153U 0156U 0157U 0158U 0159U 0160U 0161U 0162U 81277 81307 81308 81522 81542 81552 Effective 01/01/2020, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 0140U 0141U 0142U 0151U 0152U 0154U 0155U 81309 87563 Effective 01/01/2020, the following procedure codes have been deleted: 0009M, 0081U Effective 01/01/2020, the narratives for the following procedure codes have been revised: 0011M, 81350, 81404, 81406, and 81407 ---------- **On January 01st, 2020, the following updates will be made to the eviCore Lab Management Clinical Guidelines. These guidelines will be used by eviCore during the utilization management reviews' (i.e. medical necessity and/or prepayment reviews) processes starting on January 01st, 2020. The updated guidelines are accessible via a link contained in the Policy section of this medical policy bulletin.**

01/01/2020 Guideline Updates for eviCore Lab Management Program (Policy #: 06.02.52o)
Executive Summary of Changes

There are 07 new guidelines. 40 existing guidelines have been revised (including 18 with substantive criteria changes). One guideline was retired. See the below tables for details.

Procedure code 0098U is changing from an eligible position to the position of experimental/investigational and, therefore, not covered.

Below is a summary of the guideline changes

New Guidelines:

Spinocerebellar Ataxia Genetic Testing

1. Friedreich Ataxia Genetic Testing
2. Hereditary Ataxia Multigene Panel Testing
3. Whole Genome Sequencing
4. Hemoglobinopathies Genetic Testing
5. Myotonic Dystrophy Type 1 Genetic Testing
6. Somatic Mutation Testing - Hematological Malignancies
7.

Retired Guidelines:

8. Fragile X Associated Tremor/Ataxia Syndrome Testing

Criteria Updates (Substantive):

1. BCR-ABL Testing for Chronic Myeloid Leukemia
2. BRAF Testing for Colorectal Cancer
3. BRAF Testing for Melanoma Kinase Inhibitor Response
4. BRCA Analysis
5. CYP2D6 Variant Analysis for Tamoxifen, Tetrabenazine, or Eliglustat
6. Cystic Fibrosis Testing
7. Early Onset Familial Alzheimer Disease (EOFAD.) Genetic Testing
8. Fragile X Syndrome Testing
9. Genetic Testing for Hereditary Pancreatitis
10. Genitourinary Conditions Molecular Testing (Previously Sexually Transmitted Infections: Molecular)
11. Hereditary Hemochromatosis Testing
12. Investigational and Experimental Molecular/Genomic
13. KRAS Testing for Anti-EGFR Response in Metastatic Colorectal Cancer
14. Molecular Gastrointestinal Pathogen Panel (GIPP) Testing
15. Multiple Endocrine Neoplasia Type 1 (MEN1)
16. Niemann Pick, Type C Testing
17. Spinal Muscular Atrophy Testing
18. Laboratory Claim Reimbursement
    1.

Criteria Updates (Non-Substantive)

1. APOE Variant Analysis for Alzheimer Disease
2. Ashkenazi Jewish Carrier Screening
3. Ataxia-Telangiectasia
4. Chromosomal Microarray for Prenatal Diagnosis

	5. Factor II/Prothrombin Testing for Thrombophilia 6. Genetic Testing for Carrier Status 7. Genetic Testing for Epilepsy 8. Genetic Testing for Facioscapulohumeral Muscular Dystrophy 9. Genetic Testing for Known Familial Mutations 10. Genetic Testing for Limb Girdle Muscular Dystrophy 11. Genetic Testing for Non-Medical Purposes 12. Genetic Testing to Diagnose Non-Cancer Conditions 13. Hypertrophic Cardiomyopathy Testing 14. Li-Fraumeni Syndrome Testing 15. Marfan Syndrome Genetic Testing 16. Maturity-Onset Diabetes of the Young (MODY) Testing 17. Molecular Pathology Tier 2 Molecular CPT Codes 18. Pharmacogenomic Testing for Drug Toxicity and Response 19. Thoracic Aortic Aneurysms and Dissections (TAAD) Panel Testing 20. TPMT Testing for Thiopurine Drug Response 21. UGT1A1 Mutation Analysis for Irinotecan Response 22. Amyotrophic Lateral Sclerosis (ALS) Genetic Testing ***Other Note:***(I/E = investigational & experimental) -- **See the tables below that follow (which provide more details for the guideline changes):**

New Guidelines:

Guideline Name	Guideline #	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change
Spinocerebellar Ataxia Genetic Testing	MOL.TS.311.A	New Guideline - covered with criteria	New Guideline. This was always covered with criteria; however, was addressed by a clinical use policy.
Friedreich Ataxia Genetic Testing	MOL.TS.309.A	New Guideline - covered with criteria	New Guideline. This was always covered with criteria; however, was addressed by a clinical use policy.
Hereditary Ataxia Multigene Panel Testing	MOL.TS.310.A	New Guideline - covered with criteria	New Guideline. This was always covered with criteria; however, was addressed by a clinical use policy.
Whole Genome Sequencing	MOL.TS.306.A	New Guideline - I/E	New Guideline. This was always Investigational and/Experimental; however, it was addressed by a clinical use guideline.
Hemoglobinopathies Genetic Testing	MOL.TS.308.A	New Guideline - covered with criteria	New Guideline. This was always covered with criteria; however, was addressed by a clinical use policy.
Myotonic Dystrophy Type 1 Genetic Testing	MOL.TS.312.A	New Guideline - covered with criteria	New Guideline. This was always covered with criteria; however, was addressed by a clinical use policy.
Somatic Mutation Testing - Hematological Malignancies	MOL.TS.313.A	New Guideline - covered with criteria	New Guideline. This was always covered with criteria; however, was addressed by a clinical use policy.

Retired Guidelines:

Guideline Name	Guideline #	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change
Fragile X Associated Tremor/Ataxia Syndrome Testing	MOL.TS.171.A	Retire Guideline	The information from this guideline was incorporated into the Fragile X Testing guideline. The same gene causes both conditions. The new title is FMR1-Related Disorders Genetic Testing

Criteria Updates (Substantive):

Guideline Name	Guideline #	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change
BCR-ABL Testing for Chronic Myeloid Leukemia	MOL.TS.131.A	Criteria: added criteria for BCR-ABL1 kinase domain sequencing as per NCCN recommendations; Terminology updated; Background: updated with new information; Test information: added BCR-ABL1 kinase domain sequence information; Guidelines and Evidence: NCCN updated; References: updated	Criteria added per NCCN
BRAF Testing for Colorectal Cancer	MOL.TS.133.A	Criteria: Added indication for predictive purposes. Deleted statement that testing is I/E for "BRAF mutation testing for the purpose of decision making regarding the use of anti EGFR agents" Guideline and evidence updated. References updated. Background updated.	To better align with standard of care as these tests are being performed prior to medication selection in many cases. Also to better align with eviCore tumor marker policy which allows testing of biomarkers if level of evidence of 2A in NCCN.
BRAF Testing for Melanoma Kinase Inhibitor Response	MOL.TS.134.A	Criteria: removed requirement for specific drug treatment consideration, as this is more of a first line test; Background: Broadened scope of test to BRAF V600 mutations, as more than V600E are tested;reworked language to take emphasis off of specific drugs; Test information: updated statistics, deleted detailed info regarding specific drugs and companion diagnostics but included a list of currently approved drugs as examples; Guidelines and Evidence: updated NCCN with latest version 2.2019; References: updated	To better align with standard of care as these tests are being performed prior to medication selection in many cases. Also to better align with eviCore tumor marker policy which allows testing of biomarkers if level of evidence of 2A in NCCN.
BRCA Analysis	MOL.TS.238.A	Criteria: Added "Diagnosed with three primary breast cancers at any age" as a criterion per NCCN. Criteria: moved "BRCA1/2 mutation detected by tumor profiling in the absence of germline mutation analysis" from personal history section to a separate bullet to avoid the unaffected individuals from obtaining testing based on that history. Added other considerations section to direct reader to pharmacogenomic or somatic mutation testing policy for other indications. G&E updated; References updated	Criteria added per NCCN. Other changes were done to clarify

CYP2D6 Variant Analysis for Tamoxifen, Tetrabenazine, or Eliglustat	MOL.TS.157.A	Criteria: Removed statement that all other indications are I/E and added a statement that directs reader to Pharmacogenomic policy for additional indications given that CYP2D6 may be indicated based on the FDA labels on some drugs and be coverable under our clinical use pharm policy. Updated background. Updated References	CYP2D6 is included in the FDA label for some drugs. Therefore, the guideline was updated to account for this and directs reader to the clinical use guideline for indications not addressed specially in the guideline.
Cystic Fibrosis Testing	MOL.TS.158.A	Criteria: expanded criteria to individuals with clinical CF diagnosis who need testing for identification of correct mutation-specific FDA approved therapy, expanded KFM criteria to diagnostic testing for symptomatic individuals, expanded Intron 8 poly T analysis criteria to allow testing for individuals who have R117H, clarified criterion in sequencing section "Infants with an elevated IRT value on newborn screening and 0 or 1 mutations identified on standard panel testing" (previously said 'negative' panel); Background: updated statistics, FDA-approved medication list, added new terminology (CFSP-ID or CF screen positive - inconclusive diagnosis); Guidelines and Evidence: updated ACOG, ASRM/SMRU, and CF Foundation recommendations; References: updated	FDA-approved indications were not originally addressed in the guideline, but testing for this indication was previously approvable under the clinical use pharmacogenomics policy.
Early Onset Familial Alzheimer Disease (EOFAD.) Genetic Testing	MOL.TS.162.A	Criteria: Added coverage criteria for multigene panels based on expert review and opinion on how testing is currently requested and performed; Updated background	Based on subject matter expert review regarding how testing is currently requested and performed;
Fragile X Syndrome Testing	MOL.TS.172.A	Criteria: Added "Males and females 50 years of age or older with white matter lesions on MRI in the middle cerebellar peduncles and/or brain stem, or Males and females 50 years of age or older with FXTAS-related neurologic, cognitive, or behavioral difficulties," as criterion for testing based on expert review and suggestions as well as clinical features of the condition. Revamped the entire policy to include FXTAS as well as premature ovarian failure (POI) as indications. Also clarified that for carrier screening, the individual has to be 18 years of age or older and at risk of inheriting the mutation based on their family history. Changed title to reflect changes. FMR1-Related Disorders (Fragile X) Genetic Testing.	Based on subject matter expert review as well as clinical features of the condition
Genetic Testing for Hereditary Pancreatitis	MOL.TS.287.A	Criteria: extensive revisions to allow for panel testing which is current standard practice per expert review, restrict single gene testing to PRSS1 - the most commonly mutated gene, amend genes included on the I&E list (remove CASR and CPA1, add PNLIP and CEL) based on current literature, Added billing and reimbursement section to address panel testing; Guidelines and Evidence: update United European Gastroenterology guideline, update list of risk factor genes; References: updated	Current standard practice per subject matter expert

Genitourinary Conditions Molecular Testing (Previously Sexually Transmitted Infections: Molecular)	MOL.CS.106.A	Updated chlamydia (87490 and 87491) and gonorrhea (87590 and 87591) testing criteria to continue to allow for 3 units per DOS, but removed the modifier 59 requirement for additional units over 1. This aligns eviCore with CMS MUEs for these tests.	This aligns eviCore with CMS MUEs for these tests.
Hereditary Hemochromatosis Testing	MOL.TS.183.A	Criteria: added criteria for sequencing and del/dup in tiered fashion for higher sensitivity in members of non-northern European ancestry; Title and language throughout the policy updated from 'hereditary hemochromatosis' to 'HFE hemochromotosis' to reflect current clinical terminology; CPT table: added HFE sequencing and del/dup; Test information: added bullet about HFE sequencing and del/dup; Background and References: updated	Testing methodologies were not originally included in guideline.
Investigational and Experimental Molecular/Genomic	MOL.CU.117.I	Removed WGS and Rapid WGS since they are in test-specific policy; Removed GeneSightRx Psychotropic since this is in test-specific policy; Removed ColoPrint, miRInform Pancreas Test, and C-GAAP because they are off the market; Updated names of Rosetta Kidney (previously mi-Kidney), Rosetta Lung (previously mi-Lung), Mitomic Prostate Test (previously Prostate Core Mitomic Test); Added Clonoseq; Added Accelerate PhenoTest, Molecular Microscope MMDx-Heart, Molecular Microscope MMDx-Kidney into text; Updated lab for BREVAGen; Added the following PLA codes into table and text: 0109U, 0112U, 0113U, 0114U, 0118U, 0120U, 0130U, 0131U, 0132U, 0133U, 0134U, 0135U, 0136U, 0137U, 0138U	Evidence reviews indicated tests were I/E.
KRAS Testing for Anti-EGFR Response in Metastatic Colorectal Cancer	MOL.TS.191.A	Criteria update: removed medication requirements. Now indicated in individuals with metastatic colorectal cancer with no other requirement. Background updated. G&E updated; References updated	To better align with standard of care in that these tests are being performed prior to medication selection in many cases. Also to better align with or tumor marker policy which allows testing of biomarkers if level of evidence of 2A in NCCN.
Molecular Gastrointestinal Pathogen Panel (GIPP) Testing	MOL.CS.277.A	ICD10 codes added A09 (Infectious gastroenteritis and colitis, unspecified), A04.9 (Bacteria intestinal infection, unspecified), or K52.9 (Noninfective gastroenteritis and colitis, unspecified).	Ensuring that policy accurately reflects claims rules
Multiple Endocrine Neoplasia Type 1 (MEN1)	MOL.TS.285.A	Criteria: added "Any person under the age of 30 with PHPT, pancreatic precursor lesions, or pancreatic islet tumor regardless of family history" as an indication for testing; Background updated; Guidelines and Evidence Updated; References Updated and standardized	Based on expert review as well as clinical features of the condition

Niemann Pick, Type C Testing	MOL.TS.208.A	Criteria: Clarify biochemical testing does not need to be on cultured skin fibroblasts, as this test is no longer used; Background: updated with new statistics and diagnostic tool (NP-C suspicion index), Test Information: updated to reflect current clinical practice with regard to biochemical testing (oxysterols and filipin); Guidelines and Evidence: updated with International NP-C Disease Registry recommendations from 2018; References: Updated	To reflect current clinical practice with regard to biochemical testing
Spinal Muscular Atrophy Testing	MOL.TS.225.A	Criteria: Added Zolgensma indication for SMN2 testing, added section for c.859G>C Analysis, added c.859G>C Analysis as I/E for prognostic purposes only. Updated wording for one criterion for SMN2 deletion/duplication analysis to state "Documentation is provided that SMN2 copy number is needed to obtain insurance approval for either Spinraza or Zolgensma" to ensure that the testing is being performed for the purpose of using the medication. Updated Background and Guidelines and Evidence (Zolgensma information added); References added/updated	Zolgensma is now FDA approved for individuals with SMA. This needed to be addressed in the guideline given that some payers will require genetic testing prior to approving this medication.
Laboratory Claim Reimbursement	MOL.CS.105.I	Extended PLA range in table to 0138U, Removed 0001M given that it was previously deleted by the AMA, Clarified background information. Renamed Voluntary Prior Authorization section to "Pre-Service Review of Procedures that Do Not Require Prior Authorization" and reworded this section to clarify the procedure for when codes are submitted for groups of codes and at least one requires PA.	Clarification and/or update purposes only

Criteria Updates (Non-Substantive):

Guideline Name	Guideline #	Summary of change (to be reviewed in conjunction with actual GL)	Reason for Change
APOE Variant Analysis for Alzheimer Disease	MOL.TS.128.A	Criteria change: terminology update only; Background and Test Information: updated terminology from variant to allele; Guidelines and Evidence: added ACMG Choosing Wisely; References: updated	Clarification and/or update purposes only
Ashkenazi Jewish Carrier Screening	MOL.TS.129.A	Criteria update: Updated the term "testing" to "carrier screening" for accuracy. Guidelines and evidence updated; References updated; CPT code table updated	Clarification and/or update purposes only
Ataxia-Telangiectasia	MOL.TS.130.A	Criteria: clarification of language re who can get del/dup testing when one mutation has been identified through sequencing; several language clarifications throughout, no substantive changes	Clarification and/or update purposes only
Chromosomal Microarray for Prenatal Diagnosis	MOL.TS.149.A	Criteria: language edits and billing and reimbursement CPT code additions but no substantive changes; Background: updated with new references; Guidelines and Evidence: Updates with 2016 ACOG practice bulletin; References: updated	Clarification and/or update purposes only

Factor II/Prothrombin Testing for Thrombophilia	MOL.TS.166.A	Criteria: reformatted, but no substantive changes; Guidelines and Evidence: updated and expanded with ACMG 2018 technical standard; References: updated	Clarification and/or update purposes only
Genetic Testing for Carrier Status	MOL.CU.110.A	Criteria: removed "Exclusions for multiplex carrier screening tests" given that coverage criteria for carrier screening using 81443 is listed in expanded carrier screening policy. Updated references	Clarification and/or update purposes only
Genetic Testing for Epilepsy	MOL.TS.257.A	Criteria: wording updated/added for clarification purposes only. No changes to criteria. Background updated. References updated. CPT codes updated in table at the bottom.	Clarification and/or update purposes only
Genetic Testing for Facioscapulohumeral Muscular Dystrophy	MOL.TS.290.A	Criteria: clarified language regarding D4Z4 methyation analysis result needed to proceed to SMCHD1 by amending negative to low methylation with a cut-off value added for reference (<25%); CPT Code Table: clarify descriptions to better align with AMA descriptions; Background and Test Information: minor changes in language; References: typo corrected	Clarification and/or update purposes only
Genetic Testing for Known Familial Mutations	MOL.CU.291.A	Criteria changes: none substantive - corrected typo, added 'biological' to statement about 1st, 2nd and 3rd degree relatives; References: updated to include version numbers of NCCN guidelines.	Clarification and/or update purposes only
Genetic Testing for Limb Girdle Muscular Dystrophy	MOL.TS.288.A	Criteria change: clarification of previous genetic testing to allow previous single gene test or previous different panel test as long as causative mutation or mutations were not identified; Background: minor edits, additional info added; Guidelines and Evidence: new literature added; References: updated and reordered	Clarification and/or update purposes only
Genetic Testing for Non-Medical Purposes	MOL.CU.111.A	Criteria changes: nothing substantive, Updated common trade names. deleted tests that are no longer on the market and added additional news ones.	Clarification and/or update purposes only
Genetic Testing to Diagnose Non-Cancer Conditions	MOL.CU.114.A	Criteria: updated "child" to "individual" to allow for testing affected adults for similar purposes under the special circumstances section	Clarification and/or update purposes only
Hypertrophic Cardiomyopathy Testing	MOL.TS.189.A	Criteria: In billing and reimbursement section, updated list of single genes allowed for stacked billing to those in Gene Review that reach a 4% frequency or higher; Intro: updated CPT code table to include panels and only those 4 genes for which stacked code billing is allowed; Background: minor clarification edits; G&E updated; References added	Clarification and/or update purposes only
Li-Fraumeni Syndrome Testing	MOL.TS.193.A	Criteria: clarified that an individual with a LFS tumor spectrum tumor must have a first degree relative who meets Classic LFS criteria or Chompret criteria as listed elsewhere in the criteria section; G&E updated;References updated	Clarification and/or update purposes only
Marfan Syndrome Genetic Testing	MOL.TS.202.A	Criteria update: Clarified Z score included 2.0 for aortic root enlargement. Also spelled out the greater than and less than symbols. Background updated	Clarification and/or update purposes only
Maturity-Onset Diabetes of the Young (MODY) Testing	MOL.TS.258.A	Criteria update: Clarified no "MODY" mutation was known; Background updated	Clarification and/or update purposes only

Molecular Pathology Tier 2 Molecular CPT Codes	MOL.AD.102.A	Criteria: added the following "Laboratories may not self-assign tests to Tier 2 codes that are not specifically listed as analytes by the AMA." Updated background and references.	Clarification and/or update purposes only
Pharmacogenomic Testing for Drug Toxicity and Response	MOL.CU.118.I	Criteria: Added statement "For somatic mutation testing in solid tumor tissue, see the guideline Somatic Mutation Testing - Solid Tumors" to direct readers to that policy for somatic testing. Added Complementary to title of criteria section to clarify that this is included in the policy. Added the word germline to the first sentence of the policy to clarify that this policy is for germline testing.	Clarification and/or update purposes only
Thoracic Aortic Aneurysms and Dissections (TAAD) Panel Testing	MOL.TS.227.A	Criteria: amended list of genes eligible for consideration for reimbursement if billed using stacked codes to limit to genes with mutation frequency of 2% or higher in TAAD according to Gene Review; Background and Test Information: updated with newer clinical information and terminology; Guidelines and Evidence: updated with info in evidence strength and corrected error in a direct quote; References: updated	Clarification and/or update purposes only
TPMT Testing for Thiopurine Drug Response	MOL.TS.229.A	Criteria: admin edits only, no substantive change; Test information: updated FDA resources; Guidelines and Evidence: Updated FDA label info for 6-mercaptopurine; References: updated	Clarification and/or update purposes only
UGT1A1 Mutation Analysis for Irinotecan Response	MOL.TS.231.A	Criteria: No substantive changes (wording change from testing to variant analysis only). Entire guideline updated to reflect "variant" instead of "mutation".Background updated.	Clarification and/or update purposes only
Amyotrophic Lateral Sclerosis (ALS) Genetic Testing	MOL.TS.125.A	Criteria: KFM section updated to clarify that 'No previous testing' would have to include the KFM. Updated block in criteria, renamed to "Other Considerations" and now says "Genetic testing for ALS, in the absence of a known familial mutation, is considered investigational and experimental and, therefore, not eligible for reimbursement" in order to allow for expansion analysis for KFM testing. Background updated; Guidelines and evidence updates; References updated	Clarification and/or update purposes only

REVISIONS FROM 06.02.52n:

10/01/2019	This version of the policy became effective on 10/01/2019. Effective 10/01/2019, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing precertification and prepayment reviews through the vendor): 0111U, 0113U, 0114U, 0118U, 0120U, 0129U, 0130U, 0131U, 0132U, 0133U, 0134U, 0135U, 0136U, 0137U Effective 10/01/2019, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 0109U, 0112U, and 0115U Effective 10/01/2019, the following procedure codes have been deleted: 0104U

REVISIONS FROM 06.02.52m:

07/01/2019	This version of the policy will become effective on 07/01/2019. Effective 07/01/2019, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing precertification and prepayment reviews through the vendor): 0084U 0087U 0088U 0089U 0090U 0094U 0101U 0102U 0103U 0104U Effective 07/01/2019, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 0086U 0096U 0097U 0098U 0099U 0100U Effective 07/01/2019, the following procedure codes have been deleted: 0057U ---------- **On July 01st, 2019, the following updates will be made to the eviCore Lab Management Clinical**

Guidelines. These guidelines will be used by eviCore during the utilization management reviews' (i.e. medical necessity and/or prepayment reviews) processes starting on July 01st, 2019. The updated guidelines are accessible via a link contained in the Policy section of this medical policy bulletin.

07/01/2019 Guideline Updates for eviCore Lab Management Program (Policy #: 06.02.52m)

Executive Summary of Changes

There are 07 new guidelines. 36 existing guidelines have been revised (including 26 with substantive criteria changes). Two guidelines were retired. See the below tables for details

Below is a summary of the guideline changes

***New Guidelines*:**

1. Neurofibromatosis Type 1 Genetic Testing
2. Legius Syndrome Genetic Testing
3. AlloSure for Kidney Transplant Rejection
4. AssureMDx Testing for Bladder Cancer
5. FoundationOne CDx
6. Molecular Respiratory Infection Pathogen Panel (RIPP) Testing
7. Medical Necessity Review Information Requirements

***Retired Guidelines*:**

1. BRCA Sequencing for Drug Treatment Response in Ovarian Cancer
2. EGFR Liquid Biopsy - Erlotinib and Osimertinib Response

Criteria Updates (Substantive):

1. Afirma Gene Expression Classifier for Thyroid Cancer
2. AlloMap Gene Expression Profiling For Heart Transplant Rejection
3. Amyotrophic Lateral Sclerosis (ALS) Genetic Testing
4. Ashkenazi Jewish Carrier Screening
5. BCR-ABL Negative Myeloproliferative Neoplasm Testing
6. BRCA Analysis
7. BRCA Ashkenazi Jewish Founder Mutation Testing
8. CADASIL Testing
9. ConfirmMDx for Prostate Cancer Risk Assessment
10. DecisionDX-Uveal Melanoma
11. Dentatorubral Pallidoluysian Atrophy Testing
12. EGFR Testing for Non-Small Cell Lung Cancer TKI Response
13. Expanded Carrier Screening Panels
14. Familial Hypercholesterolemia Genetic Testing
15. Flow Cytometry
16. Genitourinary Conditions Molecular Testing
17. Hereditary (germline) testing after tumor (somatic) testing
18. Investigational and Experimental Molecular/Genomic Testing
19. Liquid Biopsy Testing – Solid Tumors
20. Lynch Syndrome Tumor Screening -Second-Tier
21. Mammaprint 70-Gene Breast Cancer Recurrence Assay
22. Pharmacogenomic Testing for Drug Toxicity and Response
23. Preimplantation Genetic Screening and Diagnosis
24. Prenatal Aneuploidy FISH Testing

25. Rett Syndrome Testing
26. Spinal Muscular Atrophy Testing

Criteria Updates (Non-Substantive)

1. CYP2D6 Variant Analysis for Drug Response
2. Duchenne & Becker Muscular Dystrophy Testing
3. Factor II/Prothrombin Testing for Thrombophilia
4. Genetic Testing by Multi Gene Panels
5. Long QT Syndrome Testing
6. Lynch Syndrome Genetic Testing
7. Tumor Marker Testing - Solid Tumors
8. Whole Exome Sequencing
9. Genetic Testing for Dilated Cardiomyopathy
10. ThyraMIR and ThyGenX miRNA Gene Expression Classifier

***Other Note*:** (I/E = investigational & experimental) --

See the tables below that follow (which provide more details for the guideline changes):

New Guidelines:

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change
MOL.TS.301.A	Neurofibromatosis Type 1 Genetic Testing	New policy - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.302.A	Legius Syndrome Genetic Testing	New policy - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.307.A	AlloSure for Kidney Transplant Rejection	New policy - Investigational and/or experimental	This testing has always been I/E. However, it was previously addressed by a clinical use guideline. This is a test specific guideline.
MOL.TS.305.A	AssureMDx Testing for Bladder Cancer	New policy - Investigational and/or experimental	This testing has always been I/E. However, it was previously addressed by a clinical use guideline. This is a test specific guideline.
MOL.TS.303.A	FoundationOne CDx	New policy - covered with criteria	Change in coverage. This was previously addressed by our Tumor Marker Testing - Solid Tumors guideline and covered for individuals with NSCLC. Given the FDA approval of this test as a companion diagnostic for 5 cancer types, we added coverage criteria for the 4 additional cancer types included in the FDA label (breast, ovarian, colorectal, and melanoma)
MOL.CS.293.A	Molecular Respiratory Infection Pathogen Panel (RIPP) Testing	New policy - Claims studio	These codes are managed through claims only. Policy developed to address overuse of large panels by restricting testing to appropriate populations such as those who are immunocompromised.

MOL.AD.304.A	Medical Necessity Review Information Requirements	New administrative policy	An overarching policy that describes what information is needed for case review to help keep cases moving through the PA process and avoid being put on hold for lack of information.

Retired Guidelines

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change
MOL.TS.138.A	BRCA Sequencing for Drug Treatment Response in Ovarian Cancer	Retired	This testing is addressed by the pharmacogenomic policy. The frequent additional FDA approved indications for this test made this policy redundant to the pharmacogenomic policy.
MOL.TS.195.F	EGFR Liquid Biopsy - Erlotinib and Osimertinib Response	Retired	This testing is now addressed in the broader EGFR policy since we expanded coverage of EGFR testing via liquid biopsy to other platforms.

Criteria Changes (Substantive)

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change
MOL.TS.122.A	Afirma Gene Expression Classifier for Thyroid Cancer	Entire guideline updated to reflect new GSC test as well as the addition of the Xpression Atlas add on test. In billing section, added that CPT code 81545 is not appropriate for GSC and should only be used for the billing of the GEC.	Xpression Atlas is I/E based on evidence review, this is reflected in criteria section.
MOL.TS.123.A	AlloMap Gene Expression Profiling For Heart Transplant Rejection	Criteria - added "Medical records indicate that member has been under the care of the ordering provider within the past 30 days"	PA requests were coming in with clinic notes from 6 months prior. This criterion addition clarifies need to ensure the member's health status is current and that this testing is appropriate for them at a higher level than individual sub-criteria that impose date-limits on the information reviewed. Minimal to no impact expected on approvals/denials.
MOL.TS.125.A	Amyotrophic Lateral Sclerosis (ALS) Genetic Testing	Criteria: added targeted expansion analysis of C9orf72 as I&E (policy previously addressed only sequencing and known family mutation); Test information: added targeted expansion analysis as one of the possible test types; References: updated	Targeted expansion analysis is a possible test type that we had not included previously in the policy. Reviewers requested the information be added. For completeness, it was added.

MOL.TS.129.A	Ashkenazi Jewish Carrier Screening	Criteria: Added "The individual is of Ashkenazi Jewish ancestry" as an indication under single gene testing to clarify that testing is indicated in individuals of AJ ancestry.	This criterion was to added to clarify that Ashkenazi Jewish individuals could obtain this testing. Previously was not directly stated in the guideline.
MOL.TS.240.A	BCR-ABL Negative Myeloproliferative Neoplasm Testing	Criteria: Updated to include testing for JAK2 V617K testing for individuals without a definitive diagnosis of MPN. Updated G&E and References	This was to better align with current practice and to ensure that the appropriate individuals obtained testing. Criteria updated per review and recommendation of clinical expert.

MOL.TS.238.A	BRCA Analysis	Criteria: as per NCCN recommendation added to Personal and Family History Combination criteria ‘Dx with breast cancer at any age and relative with metastatic prostate cancer’ and ‘Dx with breast cancer at any age and relative with pancreatic cancer’, In Personal and Family HX Combo section, second to last bullet "Personal history of high-grade prostate cancer (Gleason score at least 7) at any age with ≥1 close blood relatives (on the same side of the family) with ovarian cancer at any age, pancreatic cancer at any age, metastatic prostate cancer (radiographic evidence of or biopsy proven disease) at any age, or breast cancer <50 years, and/or", added male breast cancer to the list given that the original list was intended to include those relatives with a high probability of having a BRCA mutation and men with breast cancer should be included in that list, For document clarity and efficiency, reorganized the presymptomatic criteria to remove specific criteria combinations and add that the member needed to have a first or second degree relative who meets at least one of the ‘personal history’ or ‘personal and family history combination’ criteria already listed; Guidelines and Evidence: For document efficiency removed detailed listing of NCCN criteria and replaced with a summary paragraph and deleted NCCN definitions of close blood relative, limited family history, and comprehensive genetic testing	Criteria updated to better align with NCCN.

MOL.TS.135.A	BRCA Ashkenazi Jewish Founder Mutation Testing	Criteria Update: For asymptomatic individuals, 1) clarify that both the member and the affected relative are Ashkenazi Jewish and 2) update family history of prostate cancer to delete requirement for members with additional cancer diagnoses per NCCN guidelines, plus additional clarification edits; References: updated	Criteria updated to better align with NCCN and to clairfy ethnicity requirement
MOL.TS.144.A	CADASIL Testing	Background, Test information, G&E and References updates. Criteria - added age requirement (age 18 or older) for predictive testing. Added deletion/duplication testing section. Removed requirement for skin biopsy, given that it is invasive testing. Based on expert review and to better align with how testing is done clinically.	Criteria updated to reflect expert review as well as to remove the requirement of an invasive skin biopsy test.
MOL.TS.153.A	ConfirmMDx for Prostate Cancer Risk Assessment	Literature section added, references updated. Criteria: Additional indications added under section "member is considered higher risk for prostate cancer" to better align with available literature and society recommendations.	Additions to criteria were all based on review of available literature regarding what indications are considered higher risk.
MOL.TS.254.A	DecisionDX-Uveal Melanoma	G&E and Literature review updated, and References updated. DecisionDX-UM Seq information added; DecisionDX-UM Seq added into Criteria section as I/E. Clarified that DecisionDX PRAME is I/E. Based on evidence review of available peer reviewed literature	Based on evidence review of available peer reviewed literature
MOL.TS.159.A	Dentatorubral Pallidoluysian Atrophy Testing	Background, G&E, References Updated. Criteria: clarified type of repeat testing under previous testing section. Added "Brain MRI demonstrating cerebellar and brain stem atrophy" for diagnostic testing for individuals less than 20 years. Added "Brain MRI demonstrating cerebellar and brain stem atrophy and Dementia/psychiatric disturbance" into list of symptoms for diagnostic testing for individuals 20 years of age of older. Better align with clinical practice and the symptoms exhibited by patients at different ages.	Updated to better align with clinical practice and the symptoms exhibited by patients at different ages based on review and recommendation of clinical expert.

MOL.TS.163.A	EGFR Testing for Non-Small Cell Lung Cancer TKI Response	Background and References Updated. Criteria: Added osimertinib as an indication for targeted mutation testing. removed the requirement that the cell type had to be nonsquamous. Testing exceptions removed based on recommendation of subject matter expert and to better align with broader molecular profiling coverage found in NSCLC panel policy, Added Other Considerations section to allow coverage for EGFR liquid biopsy;	Criteria section updated to reflect the coverage of EGFR testing via liquid biopsy on any platform. Other updates were based on clinical expert review and to better align with broader molecular profiling coverage found in NSCLC panel policy
MOL.TS.165.A	Expanded Carrier Screening Panels	Criteria: Included criteria for expanded carrier screening panels being billed with new CPT code 81443 added in 2019.	Addition of a new CPT code in 2019 for expanded carrier screening prompted the addition of criteria.
MOL.TS.169.A	Familial Hypercholesterolemia Genetic Testing	Criteria: criteria added for multigene panels since most labs offer this testing in panels. Also added 'if performed' after the previous testing to clarify targeted or single gene testing was not required to be performed first. Background, G&E and references updated	Criteria updated to reflect the current offerings available for the testing. Most laboratories offer this testing as a panel.
MOL.CS.103.A	Flow Cytometry	Background and References updated. Criteria updated. Limits for certain indications (for some, up to 27 flow cytometry markers) were updated per expert review and recommendation. The limit for post service review was also updated from 14 to 20 per expert review and recommendation.	Criteria updated per review and recommendation of clinical expert.
MOL.CS.106.A	Genitourinary Conditions Molecular Testing	updated HPV testing criteria based on updated USPSTF guideline	Criteria updated based on updated USPSTF guidelines stating that cervical cytology alone should be performed in women aged 21-29. HPV screening is not recommended in this age group.
MOL.CU.246.A	Hereditary (germline) testing after tumor (somatic) testing	Criteria change: variant frequency in tumor reduced to 33% (from 50%) to reflect likely frequency of a germline mutation in tumor tissue; CPT code table updated with specific gene codes for known familial variants; References updated; Admin updates	Criteria updated per review and recommendation of clinical expert.

MOL.CU.117.I	Investigational and Experimental Molecular/Genomic Testing	Removed PancraGEN and Allosure; Added INFINITI, TOXLOK, BBDRisk, and miR-31now, OncotypeDx AR-V7, added SmartGut; Added Envisia, Percepta, BioFire® FilmArray® Respiratory Panel (RP), BioFire® Diagnostics, BioFire® FilmArray® Respiratory Panel 2 (RP2), BioFire® Diagnostics	Added tests that are considered I&E based on evidence review. Removed tests that are now addressed by test-specific policy.
MOL.TS.194.I	Liquid Biopsy Testing – Solid Tumors	Criteria: Added coverage for Guardant360 panels for NSCLC; Added EGFR section that directs reader to EGFR policy for targeted mutation testing. Other consideration section - all other liquid biopsy I/E. Background updated; Test Information updated; Guidelines and Evidence updated (NCCN); References updated	Based on NCCN recommendations, clinical expert recommentaion, and literature review
MOL.TS.199.A	Lynch Syndrome Tumor Screening -Second-Tier	Criteria change: criteria amended for coverage of 'BRAF V600 codon' mutations, not just 'BRAF V600E' based on expansion of reported mutations at this hot spot; Guidelines and evidence updated; References updated	Updates based on clinical expert recommendation and review of literature.
MOL.TS.200.A	Mammaprint 70-Gene Breast Cancer Recurrence Assay	Criteria updated to reflect eviCore's new coverage guideline criteria. Tumor size and characteristics are slightly different. Amongst other criteria, new guideline has the following criteria "tumor size > 0.5cm, ER+, HER2 negative"	Coverage for this testing was updated based on review of peer reviewed literature and published society guidelines. For most clients, this testing was previously I/E. IBC was previously covering this testing; however, the criteria has changed slightly to align with eviCore's general coverage guideline.
MOL.CU.118.I	Pharmacogenomic Testing for Drug Toxicity and Response	Criteria: Removed "Testing is NOT being performed as part of a panel of genes, AND" since we are now covering the pharmacogenomic panel FoundationOne CDx	A new test-specific guideline for FoundationOne CDx was written based on the FDA approval as a companion diagnostic. This is a panel of genes. Therefore, this statement was no longer relevant.
MOL.CU.119.A	Preimplantation Genetic Screening and Diagnosis	Updated references; Criteria - added PGD for VUS is not medically necessary to align with other clinical policies. Added clarification that familial mutations need to be known in order to perform PGD	To clarify coverage for VUS since it was not specified previously. VUS are addressed by a clinical use guideline; however, for clarification, this specific information was added to this guideline

MOL.CS.218.A	Prenatal Aneuploidy FISH Testing	Since codes are managed in claims only, this was made into a claims studio policy. Removed from all clients that are not claims studio clients. Criteria: Removed requirement that results are needed in less than 1 week for pregnancy management; Added claims rules with an ICD code table	Criteria updated per review and recommendation of clinical expert. These codes are managed through claims only. Therefore, we made this a claims studio policy and added claims rules for transparency
MOL.TS.224.A	Rett Syndrome Testing	Diagnostic criteria added to background. Criteria: Added females with autism and negative Fragile X and CMA as an indication for testing per ACMG society guidelines.	Criteria updated to reflect ACMG guidelines
MOL.TS.225.A	Spinal Muscular Atrophy Testing	Criteria: Removed "Non-diagnostic results from SMN1 exon 7 deletion testing (not homozygous SMN1 deletion) in the diagnostic setting, AND" from previous testing given the new CPT codes are for either methodology; SMN1 sequencing, updated 'and' to 'or' to allow for individuals with nondiagnostic SMN1 exon deletion testing to move onto sequencing.	Updated to better align with clinical practice and the addition of a CPT code that could be for either methodology.

Criteria Changes (Non-Substantive)

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change
MOL.TS.157.A	CYP2D6 Variant Analysis for Drug Response	Removed CPT code 0028U and added 0070U through 0076U; Criteria - removed mention of CPT code 0028U. Added: "Additional CYP2D6 tests, denoted by CPT codes 0071U–0076U, are typically not medically necessary. Requests for these tests will be reviewed on a case by case basis."	No substantive criteria changes. Updates were done due to addition of PLA codes.
MOL.TS.161.A	Duchenne & Becker Muscular Dystrophy Testing	Background, G&E, and References Updated. Criteria - Previous testing methods clarified	No substantive criteria changes. Updates were done for clarification purposes only
MOL.TS.166.A	Factor II/Prothrombin Testing for Thrombophilia	Criteria: Defined recurrent pregnancy loss as 2 or more failed clinical pregnancies per ASRM and added reference	No substantive criteria changes. Updates were done for clarification purposes only

MOL.CU.116.A	Genetic Testing by Multi Gene Panels	Criteria: removed statement regarding WGS being I/E. This testing for most plans is still I/E; however, it is addressed in other policies. Added statement regarding deletion/duplication portion of panels and when the billing of 81228/81229 would be appropriate for del/dup testing	No substantive criteria changes. Updates were done for clarification purposes and to ensure consistency among eviCore clinical reviewers.
MOL.TS.196.A	Long QT Syndrome Testing	Criteria: Added billing and reimbursement section to clarify redirection to panel code and procedure if laboratory cannot redirect	No substantive criteria changes. Updates were done for clarification purposes only
MOL.TS.197.A	Lynch Syndrome Genetic Testing	Criteria Change: added exclusion of FAP as a diagnosis higher in the criteria list so it applies to both predisposition and diagnostic testing (previously only in predisposition section) and added clarifying comment in Table 1 that Per NCCN guidelines, only MLH1 promoter mutation analysis is recommended for endometrial tumors when IHC testing has indicated a loss of MLH1 protein; Background updated; References updated; Admin edits	No substantive criteria changes. Updates were done for clarification purposes only
MOL.TS.230.A	Tumor Marker Testing - Solid Tumors	Title change "Somatic Mutation Testing - Solid Tumors"; updated language throughout policy. Removed FoundationOne CDx from CPT code table since new test-specific policy is available; Added FoundationOne CDx block to direct reader to that test-specific policy.	No substantive criteria updates. Directs reader to FoudationOne CDx policy
MOL.TS.235.A	Whole Exome Sequencing	Criteria: added Prenatal WES as I&E based on literture review, deletion/duplication testing by WES called I&E in other considerations section; deleted WGS as this is addressed for most clients in the I&E Policy; Guidelines and Evidence updated; References updated	No substantive criteria changes. Updates were done for clarification purposes only. Deletion/Duplication testing and prenatal WES was always considered I/E. However, we clarified it in the policy.

MOL.TS.284.A	Genetic Testing for Dilated Cardiomyopathy	Updated background, Updated criteria section to account for various modalities to establish a diagnosis. Updated billing and reimbursement section to account for billing of panels and the inability of some labs to redirect. Updated G&E and References	No substantive criteria changes. Updates were done for clarification purposes only.
MOL.TS.259.I	ThyraMIR and ThyGenX miRNA Gene Expression Classifier	Updated the policy throughout to reflect the new name of ThyGenX. It is now called ThyGeNEXT.	No substantive criteria changes.

REVISIONS FROM 06.02.52I:

01/01/2019	This version of the policy will become effective on 01/01/2019. Effective 01/01/2019, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing precertification and prepayment reviews through the vendor): 81163 81164 81165 81166 81167 81173 81174 81185 81186 81189 81190 81286 81289 81306 81336 81337 81443 81518 0081U (**Note**: On 12/28/2018 PLA Procedure code 0081U, effective 01/01/2019, was added to this policy in Notification). Effective 01/01/2019, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 81171 81172 81177 81178 81179 81180 81181 81182 81183

81184
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Effective 01/01/2019, the narratives for the following procedure codes have been revised:

81162
81212
81215
81216
81217
81244
81287
81327
81400
81401
81403
81404
81405
81407

Effective 01/01/2019, the following procedure codes have been deleted:

81211
81213
81214

Effective 01/01/2019, the following management changes will take place for genomic testing codes that are already in effect & part of eviCore Lab Management Program for the Company:

-- This procedure code will be managed through prepayment review only:

81287

-- These procedure codes will be managed through precertification in addition to prepayment reviews:

81202
81221
81248
81252
81253
81258
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S3844
S3850

On January 2nd, 2019, the following updates will be made to the eviCore Lab Management Clinical Guidelines. These guidelines will be used by eviCore during the precertification and/or prepayment review processes starting on January 2nd, 2019. The updated guidelines are accessible via a link contained in the Policy section of this medical policy bulletin.

01/02/2019 Guideline Updates for eviCore Lab Management Program (Policy #: 06.02.52l)

Executive Summary of Changes

There are 20 new guidelines. 93 existing guidelines have been revised (including 32 with criteria changes); however 61 of these were changes in the background sections of the guidelines only. See the below tables for details. Two guidelines were retired.

Below is a summary of the guideline changes

***New Guidelines*:**

1. Genetic Testing for Autism
2. Genetic Testing for Arrhythmogenic Right Ventricular Cardiomyopathy
3. DermTech Pigmented Lesion Assay
4. RosettaGX Reveal
5. Genetic Testing for Dilated Cardiomyopathy
6. Multiple Endocrine Neoplasia Type 1 (MEN1)
7. Multiple Endocrine Neoplasia Type 2 (MEN2)
8. Genetic Testing for Hereditary Pancreatitis
9. Genetic Testing for Limb Girdle Muscular Dystrophy
10. Chromosome Analysis for Reproductive Disorders, Prenatal testing, and Developmental Disorders
11. Genetic Testing for Facioscapulohumeral Muscular Dystrophy
12. Genetic Testing for Known Familial Mutations
13. Genetic Testing for Variants of Uncertain Clinical Significance
14. Decipher Prostate Cancer Classifier

15. OncotypeDX for Prostate Cancer
16. ProMark
17. Prolaris
18. Genetic Presymptomatic and Predictive Testing for Adult-Onset Conditions in Minors
19. Macula Risk
20. EGFR Liquid Biopsy - Erlotinib and Osimertinib Response

***Retired Guidelines*:**

1. Gene Expression Profiling Tests for Prostate Cancer
2. Prenatal Chromosome Analysis

Criteria Updates:

1. Angelman Syndrome Testing
2. BRAF Testing for Melanoma Kinase Inhibitor Response
3. BRCA Analysis
4. BRCA Ashkenazi Jewish Founder Mutation Testing
5. Chromosomal Microarray Testing For Developmental Disorders
6. ConfirmMDx for Prostate Cancer Risk Assessment
7. Cystic Fibrosis Testing
8. Ehlers Danlos Syndrome Testing
9. Hereditary Connective Tissue Disorder Testing
10. Investigational and Experimental Molecular/Genomic Testing
11. Li-Fraumeni Syndrome Testing
12. Lynch Syndrome Tumor Screening - First-Tier
13. Maturity-Onset Diabetes of the Young (MODY) Testing
14. Non.Invasive Prenatal Testing
15. PALB2 Genetic Testing
16. Peutz-Jeghers Syndrome Testing
17. Prader-Willi Syndrome Testing
18. Lynch Syndrome Genetic Testing
19. Acute Myeloid Leukemia (AML) Genetic Testing
20. Brugada Syndrome Genetic Testing
21. Genetic Testing for Non-Medical Purposes
22. Genetic Testing to Predict Disease Risk
23. Laboratory Claim Reimbursement
24. Marfan Syndrome Genetic Testing
25. Thoracic Aortic Aneurysms and Dissections (TAAD) Panel Testing
26. Genetic Testing for Cancer Susceptibility and Hereditary Cancer Syndromes
27. Genetic Testing for Carrier Status
28. Genetic Testing for Prenatal Screening and Diagnostic Testing
29. Genetic Testing for the Screening, Diagnosis, and Monitoring of Cancer
30. Genetic Testing to Diagnose Non-Cancer Conditions
31. ThyGenX and ThyraMIR miRNA Gene Expression Classifier
32. ThyroSeq

Background Updates only (no criteria updates):

See details for these changes in the table below.

***Other Changes*:** (I/E = investigational & experimental) --

	See the tables below that follow (which provide more details for the guideline changes):

***New Guidelines*:**

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change
MOL.TS.269.A	Genetic Testing for Autism	New guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline. Panels are, however, considered not medically necessary and not reimbursable.
MOL.TS.281.A	Genetic Testing for Arrhythmogenic Right Ventricular Cardiomyopathy	New guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.282.A	DermTech Pigmented Lesion Assay	New guideline - remained Investigational and/or experimental	This testing has always been I/E. However, it was previously addressed by a clinical use guideline. This is a test specific guideline.
MOL.TS.283.A	RosettaGX Reveal	New guideline - remained Investigational and/or experimental	This testing has always been I/E. However, it was previously addressed by a clinical use guideline. This is a test specific guideline.
MOL.TS.284.A	Genetic Testing for Dilated Cardiomyopathy	New guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.285.A	Multiple Endocrine Neoplasia Type 1 (MEN1)	New guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.286.A	Multiple Endocrine Neoplasia Type 2 (MEN2)	New guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.287.A	Genetic Testing for Hereditary Pancreatitis	New guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.288.A	Genetic Testing for Limb Girdle Muscular Dystrophy	New guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.

MOL.CS.289.A	Chromosome Analysis for Reproductive Disorders, Prenatal testing, and Developmental Disorders	New Claims Studio guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline for Claims Studio clients.
MOL.TS.290.A	Genetic Testing for Facioscapulohumeral Muscular Dystrophy	New guideline - covered with criteria	Testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.CU.291.A	Genetic Testing for Known Familial Mutations	New clinical use guideline	New clinical use guideline
MOL.CU.292.A	Genetic Testing for Variants of Uncertain Clinical Significance	New clinical use guideline	New clinical use guideline
MOL.TS.294.A	Decipher Prostate Cancer Classifier	New guideline- remained Investigational and/or experimental	This testing has always been I/E. However, it was previously addressed by a broader Gene Expression Profiling Tests for Prostate Cancer guideline. This is a test specific guideline.
MOL.TS.295.A	OncotypeDX for Prostate Cancer	New guideline - remained Investigational and/or experimental; updated OncotypeDX CPT to 0047U	This testing has always been I/E. However, it was previously addressed by a broader Gene Expression Profiling Tests for Prostate Cancer guideline. This is a test specific guideline.
MOL.TS.296.A	ProMark	New guideline - remained Investigational and/or experimental	This testing has always been I/E. However, it was previously addressed by a broader Gene Expression Profiling Tests for Prostate Cancer guideline. This is a test specific guideline.
MOL.TS.297.A	Prolaris	New guideline - remained Investigational and/or experimental	This testing has always been I/E. However, it was previously addressed by a broader Gene Expression Profiling Tests for Prostate Cancer guideline. This is a test specific guideline.
MOL.CU.298.A	Genetic Presymptomatic and Predictive Testing for Adult-Onset Conditions in Minors	New clinical use guideline	New clinical use guideline
MOL.TS.300.A	Macula Risk	New guideline - remained Investigational and/or experimental	This testing has always been I/E. However, it was previously addressed by a clinical use guideline. This is a test specific guideline.
MOL.TS.195.F	EGFR Liquid Biopsy - Erlotinib and Osimertinib Response	New guideline - covered with criteria	New guideline

***Retired Guidelines*:**

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change

MOL.TS.239.A	Gene Expression Profiling Tests for Prostate Cancer	Retired - guideline addressed 4 different tests. These 4 tests were separated into different test-specific guidelines	Retired - guideline addressed 4 different tests. These 4 tests were separated into different test-specific guidelines
MOL.TS.219.A	Prenatal Chromosome Analysis	Retired	Retired guideline. This was replaced for Claims Studio clients with the new Chromosome Analysis for Reproductive Disorders, Prenatal Testing, and Developemental Disorders guideline. This new guideline is broader.

Criteria Updates:

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change
MOL.TS.126.A	Angelman Syndrome Testing	Criteria: updated to allow both CMA and FISH testing for detection of deletions (previously FISH only) as per updated evidence; Test info update, reference updates	Previous test strategy document used as source for recommended/approvable tests was retired and not replaced; Criteria were amended to reflect current recommendations of expert authored review and disease advocacy society.
MOL.TS.134.A	BRAF Testing for Melanoma Kinase Inhibitor Response	Criteria: exclusions section removed (testing indications for multiple cancer types); New FDA indication for Mekinist; References updated	Exclusions for cancer types were removed as FDA recommends testing BRAF in cancer types other than melanoma.

MOL.TS.238.A	BRCA Analysis	Criteria: Diagnostic testing updated to expand coverage to members with personal history of pancreatic cancer and members with breast cancer who have family history of high-grade prostate cancer; KFM updated to add: If the familial mutation is not one of the three Ashkenazi Jewish mutations, then known familial mutation analysis for that mutation should be performed in addition to the founder mutation panel. Criteria added to personal and family hx section under Initial breast cancer diagnosis at any age and one or more of the following: "A close blood relative (first-, second-, or third- degree) with a triple negative breast cancer (ER-, PR-, Her2-) occurring at age 60 or younger, and/or". Also updated the criteria for individuals with a personal history of high grade prostate cancer and additional family history to align with the new NCCN guidelines.	Expanded diagnostic testing and known family mutation testing coverage to align more closely with current NCCN recommendations
MOL.TS.135.A	BRCA Ashkenazi Jewish Founder Mutation Testing	Criteria Diagnostic Testing update: coverage expanded to personal history of high-grade prostate cancer without additional family history	Expanded diagnostic testing coverage to align more closely with current NCCN recommendations
MOL.TS.150.A	Chromosomal Microarray Testing For Developmental Disorders	Administrative edits; Criteria change: allow for fetal loss at 20 weeks or later per ACOG and MFM Society rec (prev. 3rd trimester); Guidelines and evidence updated; references updated	Criteria for chromosome testing after fetal loss updated to align with ACOG and Maternal Fetal Medicine Society recommendations
MOL.TS.153.A	ConfirmMDx for Prostate Cancer Risk Assessment	Criteria update: added HOXB13 (G84E mutation carriers) to list of genes associated with increased risk of prostate cancer per NCCN guidelines; Guidelines and Evidence and reference updates.	Updated criteria to align with NCCN recommendations

MOL.TS.158.A	Cystic Fibrosis Testing	Criteria update: Removed pancreatitis as an indication and entered note to direct reader to hereditary pancreatitis policy; removed redundant carrier testing criteria; clarified family history criterion for prenatal testing criteria, updated definition of intermediate sweat chloride to 30-59mmol/L in all age groups (per 2017 CFF guideline); additional admin updates, Test info and Guidelines and Evidence updates, reference updates	Criteria amended to 1) reflect creation of new pancreatitis guideline; 2) align with new clinical diagnostic criteria for sweat chloride levels in patients across all ages; 3) clarified other criteria
MOL.TS.267.A	Ehlers Danlos Syndrome Testing	Updated background; Reordered references; Criteria updated to clarify. Also added the following criterion as a covered indication for vEDS testing "Member has one minor criterion for vEDS and a family history of arterial rupture, colonic rupture, uterine rupture, or carotid-cavernous sinus fistula (CCSF)" Clarified that panel testing is addressed in the HCTD guidelines. Removed tiering of testing and updated sequencing to reflect that change. Verbiage changed from "Analysis" to "Sequencing".	Criteria expanded for vascular EDS testing based on evidence review and recommendation of clinical expert.
MOL.TS.268.A	Hereditary Connective Tissue Disorder Testing	CPT code table updated; Admin edits; Updated criteria to clarify the non-covered indications and expanded indications for testing of individuals suspected of having a connective tissue disorder	Criteria amended to include individuals suspected to have connective tissue disorder in addition to those with a diagnosis to more fully capture members who will benefit from change in medical management based on test results. Guideline was reviewed by national clinical expert.
MOL.CU.117.I	Investigational and Experimental Molecular/Genomic Testing	Added Allosure; Added PCR Fungal Screen for Onychomycosis; removed CPT codes from text; Added test names and CPT codes to table at beginning of guideline; removed macula risk since we have test specific guideline; Also removed 87506 and 87507 since it is addressed by GIPP Claims Studio guideline. For all versions of I/E policy, added CPTs 0053U, 0055U, 0056U, 0057U and 0060U and associated test information.	Added tests that are considered I&E based on evidence review (AlloSure); removed tests that now have criteria or are now addressed by a test-specific guideline (Macula Risk).

MOL.TS.193.A	Li-Fraumeni Syndrome Testing	Updates to "sequence analysis" section. Version number and year updated in NCCN reference; Criteria: Added the following indication to diagnostic testing Individual with a tumor from LFS tumor spectrum and one or more biologic relatives (1st, 2nd, or 3rd degree) with a clinical diagnosis of LFS/LFL (according to criteria above) and no known family mutation or no testing to date	Expanded diagnostic testing criteria to include specific personal and family history combination as this was not included previously.
MOL.TS.198.A	Lynch Syndrome Tumor Screening - First-Tier	Removed "Lynch Syndrome tumor screening may be considered for individuals with Lynch syndrome-related cancer according to the revised Bethesda criteria and guidelines from the National Comprehensive Care Network (NCCN)." and the list of LS cancers from criteria since it was not an actual list of criteria. NCCN guideline information updated.	Removed redundant information in the criteria section. However, no change to criteria
MOL.TS.258.A	Maturity-Onset Diabetes of the Young (MODY) Testing	Criteria change: age at diagnosis changed from 25 or younger to younger than 35 years; background updated with new Gene Review; Policy format standardized; reference links updated	Criteria for age at diagnosis amended based on peer reviewed literature (25 to 35)
MOL.TS.209.A	Non.Invasive Prenatal Testing	Added single gene testing into CPT code table; Criteria update: Clarified that microdeletion testing is I/E; added single gene testing is I/E. Rearranged the guidelines and evidence section. 1.In the Guidelines section, under the ISPD section (near the end), their is a statement that says "options 4-9 below", this was removed since the statement did not include 4-9.	I&E classification of microdeletion NIPT clarified; Single Gene NIPT added as I/E per literature review
MOL.TS.251.A	PALB2 Genetic Testing	Codes added under procedure table. Content added under g & e section. Content added under criteria for deletion/duplication testing. Updates to references.	Added criteria for deletion/duplication testing
MOL.TS.216.A	Peutz-Jeghers Syndrome Testing	Criteria section reformatted into our standard template, but no change to clinical coverage for testing; reference update.	Criteria section restructured to align with standard format; no change in coverage

MOL.TS.217.A	Prader-Willi Syndrome Testing	Criteria Change: allow CMA or FISH for deletion analysis (previously FISH only) per updated Gene Review; Test info update, reference updates	Previous test strategy document used as source for recommended/approvable tests was retired and not replaced; Criteria were amended to reflect current recommendations of expert authored review and disease advocacy society.
MOL.TS.197.A	Lynch Syndrome Genetic Testing	Updated references and NCCN; Added the following criteria under other LS related cancers: Endometrial cancer diagnosed at any age with abnormal tumor testing indicative of a mutation in a mismatch repair gene	Tumor testing is performed on endometrial cancers. This criteria was updated to reflect possible results from tumor testing
MOL.TS.274.A	Acute Myeloid Leukemia (AML) Genetic Testing	administrative edits; Updated CPT code table, added 0046U, 0049U, 0050U; removed eviCore name in billing and reimbursement consideration section and updated to say "the laboratory will be redirected to the appropriate panel code(s)."	The language was updated to remain consistent with other guidelines. No changes to coverage criteria.
MOL.TS.261.A	Brugada Syndrome Genetic Testing	Incidence added. Verbiage updated. Criteria language updated "No previous sequence analysis of SCN5A"	Criteria updated to clarify previous testing section
MOL.CU.111.A	Genetic Testing for Non-Medical Purposes	Removed the language "Test-specific policies" from criteria from header since the list was not a list of actual policies. Also updated language to clarify that the testing is not reimbursable. Now says "The following types of testing are not considered medically necessary and therefore, not eligible for reimbursement:"	Background information updates; Criteria language updated, but no changes to coverage.
MOL.CU.115.A	Genetic Testing to Predict Disease Risk	Updated criteria: test specific guideline section to remove reference to guideline manual	Criteria language updated, but no changes to coverage.

MOL.CS.105.I	Laboratory Claim Reimbursement	CPT code additions- MAAA up to 0013M, PLA up to 0060U, 0500T addded,G0464 deleted ; admin edits for clarification; criteria edits- reworded the following for clarity,edits did not change For Maximum Units per Date of Service-- 1.The allowable daily maximum units for a procedure code are not reliant on medical necessity policy. They may only be addressed in this table and nowhere else in any other policy. 2. Total billed units are calculated based on the combined number of times a procedure code is billed on a single date of service. This applies to codes billed with multiple units on a single claim line, units reported on separate claims lines on the same claim, or multiple units reported on separate claims for that date of service. All maximum unit rules are applied per date of service and do not allow additional units simply because they are billed on separate claim lines. For CCI Code Pair edits, 1. changed heading and criterion to reflect updated name " NCCI PTP Coding Edits" and 2. added "should commonly be billed together" for clarity	Criteria amended for clarity purposes; no change to coverage
MOL.TS.202.A	Marfan Syndrome Genetic Testing	Criteria: updated for consistency only to include 'Rendering laboratory is a qualified provider of service per the Health Plan policy." ; guidelines and evidence and references updated.	Criteria updated to align with eviCore standard; no change in coverage
MOL.TS.227.A	Thoracic Aortic Aneurysms and Dissections (TAAD) Panel Testing	CPT code table updated; CSANZ CV Genetic Dz Council guideline added; References updated; small clarifying addition to criteria language (KFM section) - no change operationally to criteria	Criteria updated to clarify language regarding known familial mutation testing, no change to coverage
MOL.CU.109.A	Genetic Testing for Cancer Susceptibility and Hereditary Cancer Syndromes	Updated word "policy" to "guideline" and removed reference to list of test-specific guidelines in the guideline manual;	Background information updates; Criteria language updated, but no changes to coverage.

MOL.CU.110.A	Genetic Testing for Carrier Status	Added language and applicable references. Added three references under Routine Carrier Screening section; Removed reference to list of test-specific guidelines in the guideline manua	Background information updates; Criteria language updated, but no changes to coverage.
MOL.CU.112.A	Genetic Testing for Prenatal Screening and Diagnostic Testing	Updated word "policy" to "guideline" and removed reference to list of test-specific guidelines in the guideline manual; Updated ACOG reference	Background information updates; Criteria language updated, but no changes to coverage.
MOL.CU.113.A	Genetic Testing for the Screening, Diagnosis, and Monitoring of Cancer	Updated word policy to guideline and removed reference to list of test-specific guidelines in the guideline manual	Background information updates; Criteria language updated, but no changes to coverage.
MOL.CU.114.A	Genetic Testing to Diagnose Non-Cancer Conditions	Changed verbiage from "carrier status" to "mutation status". Updated word "policies" to "guidelines" and removed reference to table of contents in guideline manual.	Background information updates; Criteria language updated, but no changes to coverage.
MOL.TS.259.I	ThyGenX and ThyraMIR miRNA Gene Expression Classifier	Guidelines and evidence updated; References updated; coverage criteria added	Background information updates; coverage changed. Testing previously I/E. Now covered with criteria.
MOL.TS.270.I	ThyroSeq	Guidelines and evidence updated; References updated; coverage criteria added	Background information updates; Testing previously I/E. Now covered with criteria.

Background Updates only (no criteria updates):

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change
MOL.TS.122.A	Afirma Gene Expression Classifier for Thyroid Cancer	Updated entire guideline to address GEC or GSC version of the Afirma classifier test; Guidelines and Evidence and References sections updated; no criteria changes affecting eligibility or reimbursement.	Laboratory is in the process of transitioning test platforms; guidelines were updated to accommodate either platform during this time
MOL.CS.106.A	Genitourinary Conditions Molecular Testing	Guidelines and evidence section added. No criteria changes	Background information updates; no criteria changes
MOL.TS.149.A	Chromosomal Microarray for Prenatal Diagnosis	Administrative edits	Administrative edits only
MOL.TS.257.A	Genetic Testing for Epilepsy	Guidelines and Evidence updated; References Updated; Table in criteria updated to include guideline name and number. No criteria changes re eligibility for testing.	Updated and expanded table within criteria; no change to eligibility

MOL.TS.125.A	Amyotrophic Lateral Sclerosis (ALS) Genetic Testing	Background updated; references added and updated; table amended to include only the most common ALS genes; no criteria changes	Background information updates; no criteria changes
MOL.TS.240.A	BCR-ABL Negative Myeloproliferative Neoplasm Testing	Updated NCCN guidelines	Background information updates; no criteria changes
MOL.TS.131.A	BCR-ABL Testing for Chronic Myeloid Leukemia	Updated the year of the NCCN section. Updated the version and year of the NCCN reference in reference #2. added 0040U to CPT code table	CPT code updates; background information updates; no criteria changes
MOL.TS.133.A	BRAF Testing for Colorectal Cancer	Updated the year under the NCCN section. Updated references	Background information updates; no criteria changes
MOL.TS.138.A	BRCA Sequencing for Drug Treatment Response in Ovarian Cancer	Statistics and reference updates; no criteria changes	Background information updates; no criteria changes
MOL.TS.248.B	Breast Cancer Index for Breast Cancer Prognosis	Added St. Gallens Guidelines and updated references	Background information updates; no criteria changes
MOLTS.148.A	Charcot-Marie-Tooth Neuropathy Testing	CPT codes for known familial mutation analysis added to the table of procedures addressed	CPT code updates; no criteria changes
MOL.TS.154.A	Corus CAD for Obstructive Coronary Artery Disease)	References updated only; no criteria changes	Background information updates; no criteria changes
MOL.TS.236.A	Cxbladder	Updated NCCN; added MAAA codes 0012M, 0013M	CPT code updates; background information updates; no criteria changes
MOL.TS.155.A	CYP2C19 Variant Analysis for Clopidogrel Response	Clinical Trials information added; no change in criteria	Background information updates; no criteria changes
MOL.TS.156.A	CYP2C9 and VKORC1 Testing for Warfarin Response	CPT code added; Bullets added in first few sections	CPT code updates; background information updates; no criteria changes
MOL.TS.157.A	CYP2D6 Variant Analysis for Drug Response	Guidelines and evidence updated; References updated; no criteria changes	Background information updates; no criteria changes
MOL.TS.254.A	DecisionDX-Uveal Melanoma	Added NCCN Uveal Melanoma guideline; updated references; no criteria changes	Background information updates; no criteria changes
MOL.TS.234.A	EndoPredict for Breast Cancer Prognosis	Updated Guidelines and evidence section and references	Background information updates; no criteria changes
MOL.TS.168.A	Familial Adenomatous Polyposis Testing	Guidelines and Evidence and reference update; no criteria changes	Background information updates; no criteria changes
MOL.TS.169.A	Familial Hypercholesterolemia Testing	Reference links updated	Background information updates; no criteria changes
MOL.TS.170.A	Familial Malignant Melanoma Testing	NCCN version & year updated in the reference section.	Background information updates; no criteria changes
MOL.TS.172.A	Fragile X Syndrome Testing	Test Information, Guidelines and Evidence, and References updated; no criteria changes.	Background information updates; no criteria changes

MOL.CU.246.A	Hereditary (germline) testing after tumor (somatic) testing	NCCN updated; Reference links updated	Background information updates; no criteria changes
MOL.TS.182.A	Hereditary Cancer Syndrome Multigene Panels	Version number and year updated in NCCN reference.	Background information updates; no criteria changes
MOL.CU.185.A	HIV Tropism Testing for Maraviroc Response	Reference links updated	Background information updates; no criteria changes
MOL.TS.187.A	HLA-B*5701 Genotyping for Abacavir Hypersensitivity	Updated language in backgound & updated reference links.	Background information updates; no criteria changes
MOL.TS.189.A	Hypertrophic Cardiomyopathy Testing	Guidelines and evidence updated; References updated; no criteria changes	Background information updates; no criteria changes
MOL.CS.104.A	Immunohistochemistry (IHC)	Updated an NCCN reference.	Background information updates; no criteria changes
MOL.TS.191.A	KRAS Testing for Anti.EGFR Response in Metastatic Colorectal Cancer	Guidelines and Evidence and References updated; no criteria changes	Background information updates; no criteria changes
MOL.TS.192.A	Leber Hereditary Optic Neuropathy (LHON) Genetic Testing	grammatical edits only	Administrative edits only
MOL.TS.194.I	Liquid Biopsy Testing – Solid Tumors	Added 0011M to the CPT code table	CPT code updates; background information updates; no criteria changes
MOL.TS.196.A	Long QT Syndrome Testing	Guidelines and evidence updated: added 2015 ESC guideline; updated references; no criteria changes	Background information updates; no criteria changes
MOL.TS.199.A	Lynch Syndrome Tumor Screening -Second-Tier	Updated NCCN reference; Updated guidelines and evidence section	Background information updates; no criteria changes
MOL.TS.200.I	Mammaprint 70-Gene Breast Cancer Recurrence Assay	Updated Guidelines and Evidence section and References	Background information updates; no criteria changes
MOL.TS.201.A	Mammostrat Breast Cancer Recurrence Assay	Annual update; no criteria changes	annual updates; no criteria changes
MOL.TS.244.A	Mitochondrial DNA Deletion Syndromes	clarifying edits to background	Background information updates; no criteria changes
MOL.TS.204.A	Mitochondrial Encephalomyopathy, Lactic Acidosis, and Stroke-like Episodes (MELAS) Genetic	multiple admin edits to definition section; no criteria changes	Background information updates; no criteria changes
MOL.TS.243.A	Mitochondrial Neurogastrointestinal Encephalopathy (MNGIE)	Reference 3 updated with journal name and year updated to 2011; Updated background with clarifying information	Background information updates; no criteria changes
MOL.AD.102.A	Molecular Pathology Tier 2 Molecular CPT Codes	Admin edits	Administrative edits only
MOL.TS.206.A	MUTYH Associated Polyposis Testing	Admin edits; Guidelines and evidence updated; Reference updates; no criteria changes	Background information updates; no criteria changes
MOL.TS.242.A	Myoclonic Epilepsy with Ragged Red Fibers (MERRF)	Updated to add clarifying language to background	Background information updates; no criteria changes

MOL.TS.245.A	Neurogenic Muscle Weakness, Ataxia, and Retinitis Pigmentosa (NARP)	Background updated; admin edits; references updated	Background information updates; no criteria changes
MOL.TS.208.A	Niemann Pick, Type C Testing	admin edit in test information section for clarification	Administrative edits only
MOL.TS.255.A	OncotypeDX Breast DCIS	NCCN updated; added 0045U into CPT code table	CPT code updates; background information updates; no criteria changes
MOL.TS.211.I	OncotypeDX for Breast Cancer Prognosis	NCCN updated; References updated	Background information updates; no criteria changes
MOL.TS.213.A	OncotypeDX for Colorectal Cancer Recurrence Risk	Removed reference to Palmetto as well as text in document. Reference not available anymore; updated reference links	Background information updates; no criteria changes
MOL.TS.215.A	PCA3 Testing for Prostate Cancer	Reference links updated	Background information updates; no criteria changes
MOL.TS.223.A	PTEN Hamartoma Tumor Syndromes Testing	Updated verbiage. Version number and year update in NCCN reference.	Background information updates; no criteria changes
MOL.TS.264.A	SelectMDx	References updated only; no criteria changes	Background information updates; no criteria changes
MOL.TS.164.A	Sept9 Methylation Analysis for Colorectal Cancer	Statistics updated; Guidelines and Evidence and references updated (NCCN added); no criteria changes.	Background information updates; no criteria changes
MOL.TS.226.A	Tay Sachs Disease Testing	Prenatal enzyme activity testing removed from test information section (no longer offered); no criteria edits	Background information updates; no criteria changes
MOL.TS.228.A	Tissue of Origin Testing for Cancer of Unknown Primary	Updated the years for some of the references (NCCN); updated CPT code descriptors	Background information updates; no criteria changes
MOL.TS.229.A	TPMT Testing for Thiopurine Drug Response	Replaced reference. Updated Guidelines.	Background information updates; no criteria changes
MOL.TS.230.A	Tumor Marker Testing.Solid Tumors	added 0048U MSK-impact to CPT table; Added FDA information for Foundation and Oncomine into Guidelines and evidence section	CPT code updates; background information updates; no criteria changes
MOL.TS.231.A	UGT1A1 Mutation Analysis for Irinotecan Response	Guidelines and Evidence updated; References updated; no criteria changes	Background information updates; no criteria changes
MOL.AD.107.A	Unique Test Identifier	Minor edits & an update to reference #1.	Background information updates; no criteria changes
MOL.TS.233.A	Von Hippel Lindau Disease Testing	New study added to Guidelines and Evidence; reference added; no criteria changes	Background information updates; no criteria changes
MOL.TS.222.A	Prosigna Breast Cancer Prognostic Gene Signature Assay	Updated CPT code table name to reflect proprietary name instead of CPT code description	To maintain consistency across guidelines

MOL.TS.266.A	Mitochondrial Genetic Testing	Deleted duplicate EFNS 2009 guideline; administrative edits; references updated	Administrative edits
MOL.TS.272.A	Pharmacogenomic Testing Panels for Major Depressive Disorder	Administrative edits	Administrative edits
MOL.TS.235.A	Whole Exome Sequencing	Added "or preconceptual (utilizing in-vitro fertilization with preimplantation genetic diagnosis)" to background bullet; CPT code descriptors updated	Background information updates; no criteria changes

REVISIONS FROM 06.02.52k:

10/01/2018	This version of the policy is effective as of 10/01/2018. Effective 10/01/2018, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing precertification and prepayment reviews through the vendor): 0067U, 0069U, 0070U, 0071U, 0072U, 0073U, 0074U, 0075U, 0076U, 0078U, 0079U Effective 10/01/2018, the following procedure code has been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 0068U Effective 10/01/2018, the following CPT code has been deleted from Attachment A for this policy because of their termination by AMA: 0028U

REVISIONS FROM 06.02.52j:

07/02/2018	**Note**: On 6/29/2018 this Notification was updated to reflect 07/01/2018 coding updates. Effective 07/01/2018, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing precertification and prepayment reviews through the vendor): 0045U, 0047U, 0048U, 0050U, 0053U, 0055U, 0056U, 0057U, 0060U Effective 07/01/2018, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 0046U, 0049U --- This version of the policy will become effective on 07/02/2018. **On July 2nd, 2018, the following updates will be made to the eviCore Lab Management Clinical Guidelines. These guidelines will be used by eviCore during the precertification and/or prepayment review processes starting on July 2nd, 2018. The updated guidelines are accessible via a link contained in the Policy section of this medical policy bulletin.** **07/02/2018 Guideline Updates for eviCore Lab Management Program (Policy #: 06.02.52j)**

Please note that this version of the update for the guidelines communicates, among other detailed changes, Company's continued noncoverage of the following test types, since they are experimental/investigational:

- NuSwab®, Vaginitis Plus (VG+) (A vaginae, BVAB-2, Megasphaera Type 1)
- OneSwab® (A vaginae, Megasphaera Type 1 and 2, BVAB-2)
- SureSwab® Vaginosis, Vaginitis Plus (G vaginalis, A vaginae, Megasphaera species)

Executive Summary of Changes

There are 11 new guidelines. Twenty-eight have been revised (including criteria changes); however some of these were not major criteria changes. See the below table for details. Two guidelines were retired and one was replaced with a more comprehensive eviCore guideline.

Below is a summary of the guideline changes

***New Guidelines*:**

1. Acute Myeloid Leukemia (AML) Genetic Testing
2. Mitochondrial Genetic Testing
3. Ehlers Danlos Syndrome Testing
4. Genetic Testing for Nonsyndromic Hearing Loss and Deafness
5. Hereditary Connective Tissue Disorder Testing
6. PancraGEN
7. Pharmacogenomic Testing Panels for Major Depressive Disorder
8. Polymerase Gamma (POLG) Related Disorders Genetic Testing
9. SensiGene Fetal RHD Genotyping
10. Molecular Gastrointestinal Pathogen Panel (GIPP) Testing
11. ThyroSeq

***Retired Guidelines*:**

1. PathfinderTG (replaced with eviCore guideline PancraGEN)
2. ScoliScore for Adolescent Idiopathic Scoliosis Prognosis (test is no longer on the market)

***Other Changes*:** (I/E = investigational & experimental) --

See the table below that follows:

Guideline ID	Guideline Name	Executive Summary of change	Reasoning/evidence to support the change
MOL.TS.274.A	Acute Myeloid Leukemia Genetic Testing	New Guideline; covered with criteria	This testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.266.A	Mitochondrial Genetic Testing	New Guideline; covered with criteria	This testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.267.A	Ehlers Danlos Syndrome Testing	New Guideline; covered with criteria	This testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.

MOL.TS.273.A	Genetic Testing for Nonsyndromic Hearing Loss and Deafness	New Guideline; covered with criteria	This testing has always been medically necessary when criteria are met; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.268.A	Hereditary Connective Tissue Disorder Testing	New Guideline; covered with criteria	This testing has always been covered with criteria; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.271.A	PancraGEN	New Guideline; maintains I/E	This testing has always been I/E and was previously marketed under the name Pathfinder TG. However, IBC deferred to their own policy. This guideline will replace IBCs PathfinderTG guideline.
MOL.TS.272.A	Pharmacogenomic Testing Panels for Major Depressive Disorder	New Guideline; maintains I/E	This testing has always been I/E. However, it was previously addressed by a clinical use guideline. This is a test specific guideline.
MOL.TS.276.A	Polymerase Gamma (POLG) Related Disorders Genetic Testing	New Guideline; covered with criteria	This testing has always been covered with criteria; however, it was previously addressed by a clinical use guideline. This is a test-specific guideline.
MOL.TS.275.A	SensiGene Fetal RHD Genotyping	New Guideline; maintains I/E	This testing has always been I/E. However, it was previously addressed by a clinical use guideline. This is a test specific guideline.
MOL.CS.277.A	Molecular Gastrointestinal Pathogen Panel (GIPP) Testing	New Claim Studio Guideline	New guideline as volume for this test is increasing.
MOL.TS.270.A	ThyroSeq	New Guideline; maintains I/E	This testing has always been I/E. However, it was previously addressed by a clinical use guideline. This is a test specific guideline.

MOL.CU.118.I	Pharmacogenomic Testing for Drug Toxicity and Response	Added companion diagnostic testing criteria and information into the background; Added Catechol-O-Methyltransferase (COMT) Genotype from Mayo Clinic (CPT 0032U);Cytochrome P450 1A2 Genotype from Mayo Clinic (CPT 0031U);IFNL3 rs12979860 gene variant (CPT 81283);Focused Pharmacogenomics Panel from Mayo Clinic (CPT 0029U);Seratonin Receptor Genotype (HTR2A and HTR2C) from Mayo Clinic (CPT 0033U);Thiopurine Methyltransferase (TPMT) and Nudix Hydrolase (NUDT15) Genotyping from Mayo Clinic (CPT 0034U);Warfarin Response Genotype from Mayo Clinic (CPT 0030U)	These are tests that have new tier 1 or PLA codes. Therefore, we specifically listed them in the criteria as being not reimbursable for clarity. The companion diagnostic testing information was added to clarify when this testing is appropriate; however, there was no change to how these cases are currently addressed.
MOL.TS.217.A	Prader-Willi Syndrome Testing	one instance of "and" updated to "or" under FISH analysis in criteria	The original intent was for this to be an "or" and not an "and". This was corrected.
MOL.TS.157.A	CYP2D6 Variant Analysis for Drug Response	Added 0028U PLA code and then added "CYP2D6 Genotype Cascade Mayo Clinic (0028U) is considered investigational/experimental and, therefore, not eligible for reimbursement." to the exclusion section	A new PLA code for this test was published and eviCore considers I/E. Therefore, the guideline was updated to reflect that determination.
MOL.TS.159.A	Dentatorubral Pallidoluysian Atrophy Testing	Removed "examination by …." from criteria	eviCore removed this requirement (an examination by a specialist prior to testing) from many guidelines unless society recommendations included examinations by a specialist as a requirement prior to testing.
MOL.TS.163.A	EGFR Testing for Non-Small Cell Lung Cancer TKI Response	Added "For patients whose disease progresses either on or after TKI therapy, repeat EGFR testing to identify the emergence of a T790M mutation may be considered to determine whether further treatment with osimertinib would be indicated." into criteria section. Background and references updated	This is in line with FDA product labeling

MOL.TS.238.A	BRCA Analysis	Added personal history of metastatic prostate cancer as indication; changed AJ woman to say AJ individual since males would be eligible for testing	NCCN updated their guidelines to include metastatic prostate cancer as an indication for BRCA Analysis. eviCore updated this guideline to reflect that change
MOL.CU.117.I	Investigational and Experimental Molecular/Genomic Testing	added general coverage guidance and reorganized the background sections; added the phrase "do not meet the above criteria and are not eligible for reimbursment" to the introductions to each test type in criteria; Added PAI-1. Removed 15U and 4U	Current evidence reviews reflected I/E determinations for these specific tests so they were added to this guideline
MOL.TS.148.A	Charcot-Marie-Tooth Neuropathy Testing Panel	Added information regarding various CMT testing to broaden guideline beyond panels. Updated the title to reflect the broader guideline. New title is Charcot-Marie-Tooth Neuropathy Testing. Updated CPT code table due to new panel code 81448.	Single gene and narrow panel testing has always been medically necessary when criteria are met but was previously addressed by a clinical use guideline. This testing has been added to this test specific guideline for clarity. Large, broad panels are still considered I/E in most cases.
MOL.TS.130.A	Ataxia Telangiectasia	Removed examination by …. from criteria	eviCore removed this requirement (an examination by a specialist prior to testing) from many guidelines unless society recommendations included examinations by a specialist as a requirement prior to testing.
MOL.TS.198.A	Lynch Syndrome Tumor Screening - First Tier	Updated Guidelines and Evidence section. Added Keytruda information into the background. Added criteria for individuals being considered for Keytruda usage. Removed age restriction for endometrial cancer in criteria section	Criteria updates reflect current society recommendations, product labeling, and current standard of care
MOL.TS.135.A	BRCA Ashkenazi Jewish Founder Mutation	Added personal history of metastatic prostate cancer as indication	NCCN updated their guidelines to include metastatic prostate cancer as an indication for BRCA Analysis. eviCore updated this guideline to reflect that change
MOL.CS.106.A	Sexually Transmitted Infections: Molecular	Updated title to Genitourinary Conditions Molecular Testing to more accurately reflect the content of the guideline, added HIV positive status to indications for Chlamydia, and added more information about lack of evidence to support bacterial vaginosis testing as medically necessary	One lab provider is being particularly persistent regarding appeals for BV. We wanted to provide additional clarifying statements in the guideline to support our clients during appeals. In addition, added HIV positive status to indications for asymptomatic chlamydia testing for clarity.

MOL.TS.251.A	PALB2 Genetic Testing	Updated title to PALB2 Genetic Testing for Breast Cancer Risk; updated CPT description to clarify that it is for sequencing	The title was updated to reflect the testing was for breast cancer rather than Fanconi anemia.
MOL.TS.161.A	Duchenne & Becker Muscular Dystrophy Testing	Removed "Clinical Consultation" from header in criteria since that criteria was removed in a previous update	eviCore removed the criteria in a previous update; however the header was not removed.
MOL.TS.194.I	Liquid Biopsy Testing –Solid Tumors	Added 81310 and 81270 to CPT code table at the top	These two genes were being seen in review of liquid biopsy cases for solid tumors. Therefore, we added them to the table at the top
MOL.TS.227.A	Thoracic Aortic Aneurysms and Dissections (TAAD) Panel Testing	The following statement was added: "This guideline addresses testing specifically for TAAD. Additional indications are addressed in the Hereditary Connective Tissue Disorder Testing guideline."	eviCore has a new guideline for hereditary connective tissue disorders. Given that the CPT codes may be the same, it was important to state in the TAAD guideline that additional indications were addressed in the other guideline
MOL.TS.230.A	Tumor Marker Testing Solid Tumors	Updated table at the end to include Guideline IDs	This was to provide clarity regarding which guideline was relevant
MOL.TS.126.A	Angelman Syndrome Testing	Criteria: changed the title to the Known Familial Mutation section; however, neither criteria nor meaning changed; change personal history to Diagnostic Testing for Symptomatic Individuals in criteria section to stay consistent; separated out family history criteria into UBE3A and imprinting center defects to clarify. However, no criteria changes were made.	Criteria was reorganized to make clearer; however, no criteria content changes were made
MOL.TS.146.A	Celiac Disease Testing	Removed "Consideration for genetic testing for celiac-associated HLA variants DQ2 and DQ8 is determined according to diagnostic guidelines from the American Gastroenterological Association, NIH Consensus Development Conference Statement on Celiac Disease, American College of Gastroenterology, and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition.2-5" from criteria section since it was redundant.	This was redundant in the criteria section. We list the criteria and do not need to state where it came from since this information is in the guidelines and evidence section
MOL.TS.165.A	Expanded Carrier Screening Panels	Removed lab specific list since it they change so frequently; Added Guideline IDs into the coverage table for clarity.	This was to provide clarity regarding which guideline was relevant

MOL.TS.182.A	Hereditary Cancer Syndrome Multigene Panels	Added Guideline IDs into the coverage table for clarity.	This was to provide clarity regarding which guideline was relevant
MOL.TS.248.B	Breast Cancer Index	added a missing "and" into criteria to clarify	The intent was to have an "and" in this spot. Therefore, it was added for clarity
MOL.TS.257.A	Genetic Testing for Epilepsy	Added Guideline ID's into the coverage table for clarity.	This was to provide clarity regarding which guideline was relevant
MOL.TS.125.A	Amyotrophic Lateral Sclerosis Genetic Testing	CPT code table broader in nature; added "therefore, not reimbursable" to seq/del/dup criteria to clarify that it is not reimbursable.	Minor updates; No changes to criteria
MOL.CS.105.I	Laboratory Claim Reimbursement	Added a "supporting documents" section at the end of the document directing clients that supporting documents are available at a client specific link	Added so that all of client's supporting resources are available at the same link. Please note that all of the supporting documents have not been added at this link yet.
MOL.TS.172.A	Fragile X Syndrome Testing	Added the word “unexplained” to the developmental delay criteria to clarify that testing in cases where there is a known cause for the developmental delay is not reimbursable.	This was added to clarify criteria.
MOL.TS.214.I	PathFinderTG	RETIRED	This was an IBC guideline that was directly written from the current IBC policy. However, eviCore created a new guideline that will replace this. See PancraGEN guideline.
MOL.TS.2487.A	ScoliScore for Adolescent Idiopathic Scoliosis Prognosis	RETIRED	Test is no longer on the market
MOL.TS.123.A	AlloMap Gene Expression Profiling for Heart Transplant Rejection	Moved exclusions to end of criteria sections; placed frequency considerations to after table	Minor updates; No changes to criteria
MOL.TS.166.A	Factor II/Prothrombin Testing for Thrombophilia	Removed this paragraph from criteria "Consideration for Factor II (prothrombin) G20210A genetic testing for thrombophilia is determined according to guidelines from the American College of Medical Genetics, the College of American Pathology, the National Society of Genetic Counselors, and the American College of Obstetricians and Gynecologists. "	This was redundant in the criteria section. We list the criteria and do not need to state where it came from since this information is in the guidelines and evidence section

REVISIONS FROM 06.02.52i:

04/01/2018	This version of the policy is effective as of 04/01/2018. Effective 04/01/2018, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing precertification and prepayment reviews through the vendor): 0036U, 0037U, 0012M, 0013M Effective 04/01/2018, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 0040U The following CPT codes have been deleted from Attachment A for this policy because of their termination by AMA: 0015U The following CPT codes have been deleted from Attachment B for this policy because of their termination by AMA: 0004U

REVISIONS FROM 06.02.52h:

01/02/2018	This version of the policy will become effective on 01/02/2018. **Below is a summary of the guideline changes** ***New Guidelines*:** 1. NETest 2. PALB2 Genetic Testing 3. DecisionDX-UM 4. OncotypeDX Breast DCIS 5. OncotypeDX for Breast Cancer Prognosis 6. Confirmatory Genetic Testing 7. Genetic Testing for Epilepsy 8. Maturity-Onset Diabetes of the Young (MODY) Testing 9. ThyGenX and ThyraMIR miRNA Gene Expression Classifier 10. Brugada Syndrome Genetic Testing 11. SelectMDx 12. ScoliScore for Adolescent Idiopathic Scoliosis Prognosis 13. EndoPredict for Breast Cancer Prognosis ***Retired Guidelines*:** 1. DecisionDx-UM (IBC specific version) 2. Brugada Syndrome Known Familial Mutation Analysis 3. Brugada Syndrome Sequencing 4. Brugada Syndrome Multigene Panels 5. EndoPredict (IBC specific version) ***Criteria Changes*:**

	1. Sexually Transmitted Infections: Molecular 2. BRCA Sequencing for Drug Treatment Response - Ovarian Cancer 3. Investigational and Experimental Molecular/Genomic 4. CYP2D6 Variant Analysis for Tamoxifen, Tetrabenazine, or Eliglustat 5. Genetic Testing via Multi Gene Panels 6. Fragile X Syndrome Testing 7. Li-Fraumeni Syndrome Testing 8. DPYD Variant Analysis for 5-FU Toxicity 9. Whole Exome Sequencing 10. Hereditary Cancer Syndrome Multigene Panels 11. Molecular Pathology Tier 2 Molecular CPT Codes 12. Corus CAD for Obstructive Coronary Artery Disease 13. Alpha-1-Antitrypsin Deficiency Testing 14. AlloMap Gene Expression Profiling For Heart Transplant Rejection 15. Duchenne & Becker Muscular Dystrophy Testing 16. Angelman Syndrome Testing Effective 01/01/2018, narratives for the following procedure codes have been revised in this policy due to coding updates: 81257, 81432, 81439 Effective 01/01/2018, the following procedure codes have been deleted in this policy due to coding updates: 87470, 87477, 87515 Effective 01/01/2018, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment A for this policy and will be undergoing precertification and prepayment reviews through the vendor): 81230, 81231, 81232, 81238, 81249, 81259, 81269, 81283, 81328, 81335, 81346, 81361, 81363, 81364, 81448, 81520, 81521, 81541, 81551, 0026U, 0028U, 0029U, 0030U, 0031U, 0032U, 0033U, 0034U, 0011M Effective 01/01/2018, the following procedure codes have been added in this policy due to coding updates (these codes have been added to Attachment B for this policy and will be undergoing prepayment reviews through the vendor): 81105, 81106, 81107, 81108, 81109, 81110, 81111, 81112, 81120, 81121, 81175, 81176, 81247, 81248, 81258, 81334, 81362, 87634, 87662, 0027U, 0500T

Effective 10/05/2017 this policy has been updated to the new policy template format.

Version Effective Date: 10/01/2020

Version Issued Date: 11/03/2020

Version Reissued Date: N/A