Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Medica has a number of coverage policies and utilization management policies addressing specific laboratory tests. Please refer to Attachment 1 at the end of this document for a list of those policies. If a separate policy does not exist, the following criteria apply.

Coverage Policy

Laboratory tests are COVERED when the individual test or panel:
1. Has been reviewed within Medica’s technology assessment process, is considered a covered service, and is published as a Medica Coverage or Utilization Management Policy.

<or>

2. Meets Medica’s definition of a standard laboratory test, as defined in the description section of this policy and is ordered and submitted from or under the direction of a physician.

Laboratory tests are NOT COVERED when the individual test or panel:
1. Has been reviewed within Medica’s technology assessment process, is considered investigative and therefore NOT COVERED, and is published as a Medica Coverage Policy.

<or>

2. Meet Medica’s definition of a non-standard laboratory test, as defined in the description section of this policy. These tests are not medically necessary and therefore NOT COVERED.

<or>

3. Is self-referred/submitted by the member (i.e., not ordered and submitted from or under the direction of a physician).
**Description**
Services not medically necessary are excluded from coverage. Services that are not medically necessary include, but are not limited to, services that are inconsistent with the medical standards and accepted practice parameters of the community and services that are inappropriate, in terms of type, frequency, level, setting, and duration, to the member’s diagnosis or condition.

Medica defines a standard laboratory test or panel as:
1. A test/panel performed in a CLIA-certified clinical laboratory setting (e.g., hospital laboratories; physician offices; reference laboratories contracted with multiple inpatient/outpatient facilities or multiple physician clinics)
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2. Recognized as clinically valid by at least one of the following professional organizations (Note: list may not be exhaustive):
   a. American Society of Clinical Pathology (ASCP)
   b. Association for Molecular Pathology (AMP)
   c. Clinical and Laboratory Standards Institute (CLSI)
   d. College of American Pathologists (CAP)
   e. National Committee for Clinical Laboratory Standards (NCCLS)

Medica defines a non-standard laboratory test as:
1. Not meeting the criteria of a standard laboratory test defined above,
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2. Possessing one or more of the following attributes:
   a. A test proposed for the diagnosis and/or monitoring of a condition or disease state which is inconsistent with medical standards and accepted practice parameters of the community.
   b. A test using a methodology other than that employed in standard medical practice (e.g., spectroscopy analysis instead of a standard culture for microorganisms)
   c. A test using a specimen type other than that employed in standard medical practice (e.g., a saliva specimen instead of a standard blood collection)
   d. Panels comprised of numerous analytes - a high number of which do not impart clinical utility to the diagnosis or management of the disease or condition under consideration. (e.g., a hormone panel measuring multiple analytes when two analytes are recognized as standard medical practice.)
   e. Test results reported in laboratory reporting values not recognized as national or international values employed in standard laboratory practice (e.g., low-medium-high versus micrograms/liter).

**Prior Authorization**
Prior authorization is required for testing outlined in the above Utilization Management Policies. Additionally, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.
Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
Laboratory tests are to be submitted with the Current Procedural Terminology Code (CPT) or Healthcare Common Procedure Code (HCPC) specific to the actual test or panel of tests being performed. If specific code(s) are not available an appropriate unlisted code with detailed description should be submitted. Medica reserves the right to obtain additional information on specific tests / test panels from the laboratory performing the analysis when the submitted CPT or HCPC code(s) is (are) general in nature/non-specific.

Original Policy Effective Date: 1/1/2010
Re-Review Date(s):
11/1/2012
8/1/2014 – Administrative update only
7/15/2015 – Administrative update only
10/21/2015
9/19/2018
Attachment 1: Policies Specific to Laboratory Tests

The following lists are subject to change without notice. Consult www.medica.com / Providers / Policies & Guidelines for a complete listing of Medica’s Coverage and Utilization Management Policies.

1. Antigen Leukocyte Cellular Antibody Test (ALCAT Test) for Food & Chemical Allergies
2. Apolipoprotein E (APOE) Genetic Testing for Prediction and Management of Cardiovascular Disease
3. Gene Expression Profiling Assays for Breast Cancer
4. Bladder Cancer Screening, Diagnosis and Monitoring Using Ancillary Urinary Tests
5. Blood Coagulation Home Testing Devices
6. Liquid Biopsy: Testing of Circulating Tumor Cells or Cell-Free Tumor DNA
7. Collagen Cross Links Tests as Markers of Bone Turnover
8. Cytochrome P450 (CYP450) Variant Genotyping
9. Cytotoxic Testing for Allergy Diagnosis
10. Exhaled Breath Tests for Asthma and Other Inflammatory Pulmonary Conditions: Exhaled Nitric Oxide Breath Test and Exhaled Breath Condensate pH Measurement
11. Expanded Carrier Testing for Genetic Diseases in Adults
12. Fecal Calprotectin Testing
13. Fecal/Stool DNA (sDNA) Testing for Colorectal Cancer Screening and Monitoring
14. Food Allergy/Intolerance Testing (in vitro)
15. Gene Expression Profiling Assays for Predicting Colon Cancer Recurrence Risk
17. Gene Expression Profiling for Detection of Heart Transplantation Rejection
18. Genetic and Pharmacogenetic Testing
19. Genetic Testing: ScoliScore™ TM Adolescent Idiopathic Scoliosis (AIS) Prognostic Test
21. Genetic Testing for Alzheimer Disease
22. Genetic Testing for Inherited Susceptibility to Malignant Melanoma
23. Genetic Testing for Prostate Cancer
24. Genetic Testing for Thyroid Cancer
25. Hair Analysis in the Clinical Setting
26. Health Research Institute / Pfeiffer Treatment Center Protocols
27. Human Leukocyte Antigen-DQ (HLA-DQ) Genetic Testing for Diagnosis of Celiac Disease
28. In Vitro Chemosensitivity & Chemosensitivity Assays
29. Intracellular Micronutrient Analysis: MicroNutrient Testing; Intracellular Mineral Electrolyte Analysis
30. KRAS Mutation Analysis for Predicting Response to Drug Therapy
31. Lipoprotein-Associated Phospholipase A2 (Lp-PLA2) Immunoassay for Prediction of Risk for Coronary Heart Disease or Ischemic Stroke (PLAC® Test)
32. Lipoprotein Subclass Testing for Screening, Evaluation, and Monitoring of Cardiovascular Disease
33. Methylenetetrahydrofolate Reductase (MTHFR) Gene Testing
34. Multivariate Biomarker Blood Testing for Predicting Malignancy in Women with Adnexal Mass
35. Pharmacogenetic Testing of the VKORC1 Gene for Warfarin Response
36. Pharmacogenetic Testing to Predict Toxicity to 5-Fluorouracil (5-FU)/Capecitabine-Based Chemotherapy
37. Salivary Estriol Test for Preterm Labor
38. Salivary Hormone Tests
39. Serial Dilution Endpoint Titration for Diagnosis and Treatment of Airborne Allergy
40. Serological Markers for Diagnosis and Management of Inflammatory Bowel Disease (IBD) or Irritable Bowel Syndrome (IBS)
41. Serum Drug Levels and Antibody Levels to Monitor Tumor Necrosis Factor (TNF) Inhibitors
42. Single Nucleotide Polymorphism (SNP) Genetic Testing for Assessment of Cancer Risk
43. Testing for Neutralizing Antibodies to Interferon Beta in the Management of Multiple Sclerosis
44. Urine Drug Testing (UDT) in the Outpatient Setting
45. Urine Drug Testing (UDT) for Residential Substance Abuse Treatment
46. Veristrat® Proteomic Testing
47. Whole Genome Sequencing

Medica also has the following Utilization Management Policies related to lab tests:
1. Comparative Genomic Hybridization (CGH) Microarray Testing
2. Genetic Testing for Cardiac Channelopathies
3. Genetic Testing for Cardiomyopathies
4. Genetic Testing For Hereditary Breast And / Or Ovarian Cancer (BRCA 1 and BRCA 2 Genes and BRAC Analysis® Rearrangement Test [BART])
5. Genetic Testing for Susceptibility to Colorectal Cancer (CRC) Syndromes
7. Whole Exome Sequencing