Genetic Testing for Inherited Conditions

Policy Number: 2018-101  
Effective Date: January 26, 2018

Review Date: January 26, 2018  
Next Review Date: January 26, 2019

Important Information - Please Read Before Using This Policy

UCare has developed medical policies to assist in the determination of coverage of a clinical service (such as a procedure, therapy, diagnostic test, medical device, etc.), when coverage requires determination of medical necessity. Clinical services referenced in UCare’s medical policies may not be covered by every UCare plan. Coverage is determined by federal and state regulation and by member contract materials, such as the Evidence of Coverage (EOC), Member Contract, or Member Handbook. This medical policy alone does not guarantee coverage.

Coverage is subject to the benefits or restrictions of the member’s specific plan, which will supersede this medical policy when applicable. Please refer to the end of this document to read “How Coverage Is Determined in Specific UCare Plans.”

UCare’s medical policies are periodically reviewed and updated using published clinical evidence. In addition to medical policies, UCare uses tools for determination of medical necessity that are developed by external sources, including but not limited to McKesson InterQual Criteria and Hayes Inc. Knowledge Center. This medical policy does not constitute the practice of medicine or medical advice. Treating health care providers are solely responsible for determining what care to provide to patients. Members should always consult their provider before making any decisions about medical care.

Administrative Procedure

Prior authorization IS required for genetic testing for inherited conditions. CPT® codes are listed below in the codes section.

UCare prior authorization form is available here:
https://www.ucare.org/providers/Eligibility-Authorizations/Pages/EligibilityAuth.aspx

Definitions and Scope of this Policy
Inherited conditions: Medical conditions that could be inherited from a parent of the person being tested or could be passed on to offspring of the person being tested (“germ line”)

Genetic Testing: Analysis of nuclear or mitochondrial DNA for purposes of diagnosing an inherited disease, determine risk or prognosis, selecting or designing therapies (e.g. drug or drug dose), or other purposes.

Multigene Panel Testing: Genetic tests that use next-generation sequencing to test multiple genes simultaneously. Also called multigene test and multiple-gene test.

Out-of-scope for this policy:
- Molecular or nucleic acid testing (DNA or RNA) of tumor tissue, biopsy tissue, or malignant cells
- Testing of embryonic or fetal genetic material, obtained by tissue specimen or cell-free (i.e., circulating in maternal blood)

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### Medical Necessity Criteria

**GENETIC TESTING FOR INHERITED CONDITIONS**

UCare considers genetic testing for inherited conditions as **MEDICALLY NECESSARY** to establish a diagnosis or prognosis, assess risk, or guide treatment or management when **ALL** of the following criteria are met:

1. Before testing is performed, supporting documentation is submitted to UCare by the clinician who is ordering the test **AND** will manage the patient using the results. Submitted documentation must include all of the information referenced in criteria 2-7 below.

2. Counseling of the patient must be performed by one of the following providers who must meet **at least one** of the following qualifications:
   a. Licensed in Minnesota as a genetics counselor (per Minnesota statue 147F [https://www.revisor.mn.gov/statutes/?id=147F&view=chapter](https://www.revisor.mn.gov/statutes/?id=147F&view=chapter)) or possessing substantially equivalent licensure from another state.
   b. Board-certified or board-eligible by the American Board of Medical Genetics and Genomics.
   c. Physician possessing knowledge and expertise within his/her scope of practice to appropriately order genetic testing for inherited conditions, correctly interpret test results, and appropriately use the results in clinical management.

3. The clinicians involved do not have an ownership stake or financial interest in the business entity of the laboratory performing the test.

4. The documentation referenced in #1 must include **ALL** of the following
   a. The specific test or tests to be performed, including any anticipated reflex or secondary testing, and associated codes; **AND**
   b. Detailed description of the personal or family medical history upon which the suspicion of an inherited condition is based; **AND**
c. Detailed description of how the results of testing will be used for the clinical management of the member being tested. Uses for clinical management include, but are not restricted to: treatment selection, monitoring or surveillance, behavior modification, and family planning. Clinical benefits to the member’s relatives do not fulfill this criterion; **AND**

d. Documentation that the member has been counseled and the member understood the test’s purpose, limitations, implications of the test results, and how the test result will be used to change their medical management.

e. The testing is approved by FDA and laboratory services must meet applicable requirements of CLIA (Clinical Laboratory Improvement Amendments).

5. The testing does not duplicate tests that have already been performed on the patient for the particular condition under investigation.

6. The clinical utility of the requested testing (when considered as a whole, not just a single component of the testing) has been demonstrated in **at least one** of the following

   a. Clinical practice guideline from an established national specialty society or national consensus statement; **OR**

   b. Published guidance from a government agency such as the Center for Medicare and Medicaid Services; **OR**

   c. Clinical trials that are published in a peer-reviewed, English-language medical journal that demonstrate improved clinical outcomes of the test when used in clinical management; **OR**

   d. Technology assessment by a recognized authoritative source, including but not limited to Hayes, Inc., ECRI Institute, or the Technology Evaluation Center of the Blue Cross Blue Shield Association.

7. The test is **not** on the list of services which UCare policy considers investigative/experimental/unproven.

MULTIGENE PANEL TESTING

UCare considers multigene panel testing **MEDICALLY NECESSARY** when **ANY** of the following criteria are met:

1. The specific multigene panel has been identified as being medically necessary by Medicare and is included in a National Coverage Determination (NCD) or Local Coverage Determination (LCD); **OR**

2. **ALL** of the following

   a. Sequential testing of individual genes is not practical (i.e. limited tissue availability, urgent treatment decisions pending); **AND**

   b. Identification of the genes on the panel have been demonstrated in published peer-reviewed literature to improve diagnosis, management, or clinical outcomes for the individual’s medical condition; **AND**

   c. **ALL** genes in the panel are relevant to the personal and family history of the member being tested

UCare considers genetic testing **NOT MEDICALLY NECESSARY** when **ANY** of the following criteria are met:

1. The tests will not directly impact the management of the member’s health condition.
2. Whole genome sequencing or exome sequencing.
3. When a family member has been tested for a mutation and received a result of variant of unknown significance (VUS) and this is the sole basis for performing genetic testing.
4. Direct-to-consumer genetic testing.

### Applicable Codes

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

#### CPT® Code Ranges Applicable To This Policy

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81200 to 81203</td>
<td>adenomatous polyposis coli and familial adenomatosis polyposis</td>
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<tr>
<td>81211 to 81217</td>
<td>BRCA analysis</td>
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<tr>
<td>81220 to 81224</td>
<td>cystic fibrosis gene analysis</td>
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<tr>
<td>81225 to 81231</td>
<td>cytochrome P450 gene analysis</td>
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<tr>
<td>81228 to 81229</td>
<td>microarray analysis</td>
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<tr>
<td>81161</td>
<td>Duchenne/Becker muscular dystrophy deletion analysis</td>
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<tr>
<td>81243 to 81244</td>
<td>Fragile X syndrome analysis</td>
</tr>
<tr>
<td>81248 to 81256</td>
<td>G6PD, G6PC, GBA, GJB2, GJB6, HEXA (Tay Sachs), HFE (hemochromatosis)</td>
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<tr>
<td>81257 to 81364</td>
<td>abnormal hemoglobins</td>
</tr>
<tr>
<td>81291</td>
<td>hereditary hypercoagulability</td>
</tr>
<tr>
<td>81292 to 81317</td>
<td>hereditary non-polyposis colorectal cancer, Lynch syndrome</td>
</tr>
<tr>
<td>81302 to 81304</td>
<td>Rett syndrome</td>
</tr>
<tr>
<td>81321 to 81323</td>
<td>Cowden syndrome, PTEN hamartoma tumor syndrome</td>
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<tr>
<td>81324 to 81326</td>
<td>Charcot-Marie-Tooth syndrome</td>
</tr>
<tr>
<td>81334 to 81355</td>
<td>RUNX1, SEPT9, SLCO1B1, SMPD1, SNRPN/UBE3A, SERPINA1, TPMT, TRB@, TRB@, TRG@,</td>
</tr>
<tr>
<td>81340 to 81465</td>
<td>MOLECULAR PATHOLOGY PROCEDURE LEVELS 1 - 9</td>
</tr>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
</tr>
<tr>
<td>81410 to 81412</td>
<td>Aortic disorders (e.g. Marfans)</td>
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<tr>
<td>81413 to 81414</td>
<td>Cardiac ion channelopathies (e.g. Brugada)</td>
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<tr>
<td>81415 to 81417</td>
<td>Exome sequence analysis</td>
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<tr>
<td>81425 to 81427</td>
<td>genome sequence analysis</td>
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<tr>
<td>81430 to 81431</td>
<td>hearing loss</td>
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<tr>
<td>81432 to 81439</td>
<td>hereditary breast cancer-related disorders, retinal disorders, colon cancer disorders, neuroendocrine tumor disorders, peripheral neuropathies, cardiomyopathy</td>
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<tr>
<td>81440 to 81465</td>
<td>mitochondrial genes, targeted genomic sequence analysis, mitochondrial genome</td>
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<tr>
<td>81470 to 81471</td>
<td>X-linked intellectual disability</td>
</tr>
</tbody>
</table>

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How Coverage Is Determined In Specific UCare Plans

- **Commercial**: UCare Choices/Fairview UCare Choices:
  Coverage is determined by the Member Contract. If there is a conflict between this medical policy and the individual Member Contract, the provisions of the Member Contract will govern.

- **Medicare Advantage**: UCare for Seniors (HMO Point-of-Service) and EssentiaCare (Preferred Provider Organization)
  Coverage is determined by guidance from the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) or applicable CMS Local Coverage Determination (LCD) and the applicable UCare Evidence of Coverage (EOC). This medical policy applies in the absence of CMS guidance and/or EOC language.

- **Medicaid – MinnesotaCare**: Prepaid Medical Assistance Program (PMAP), UCare Connect (non-SNP/non-integrated), Minnesota Senior Care Plus (MSC+), and MinnesotaCare
  Coverage is determined by the applicable Evidence of Coverage (also known as the “Member Handbook”) and guidance from the Minnesota Department of Human Services (DHS) Minnesota Health Care Programs (MHCP) Provider Manual. This medical policy applies if DHS coverage criteria are not available.

- **Medicare Advantage – Dual Eligible Special Needs Plan**: UCare Connect + Medicare and Minnesota Senior Health Options (MSHO)
  Medicare coverage is determined by the applicable Member Handbook (MSHO) or Evidence of Coverage (UCare Connect + Medicare) and guidance from the Centers for Medicare & Medicaid Services (CMS). This medical policy applies in the absence of CMS guidance and/or EOC language.

  Medicaid coverage is determined by the applicable Member Handbook (MSHO) or Evidence of Coverage (UCare Connect + Medicare), and guidance from the DHS MHCP Provider Manual. This medical policy applies if coverage criteria have not been determined by DHS.

Revision History