Genetic Testing – Oncology

I. Policy

University Health Alliance (UHA) will reimburse for oncology genetic testing when they are determined to be medically necessary and when they meet the medical criteria guidelines (subject to limitations and exclusions) indicated below. Within the additional limitations of this policy, only genetic testing that is for the purpose of treating a medical condition is covered.

II. Criteria/Guidelines

A. Genetic testing is covered (subject to Limitations/Exclusions and Administrative Guidelines) when all of the following criteria are met:

1. There must be a reasonable expectation based on family history, pedigree analysis, risk factors, and/or symptomatology that a genetically inherited condition exists.

2. The genotypes to be detected by a genetic test must be shown by scientifically valid methods to be associated with the occurrence of the disease.

3. The clinical utility of the test must be established (e.g., test results will influence decisions concerning disease treatment or prevention).

   a. Clinical utility refers to the ability of genetic test results, either positive or negative, to provide information that is of value in the clinical setting. The development of genetic tests that can diagnose or predict disease occurrence has far outpaced the development of interventions to treat, ameliorate, or prevent those same diseases. In the absence of such interventions, the benefits of testing are limited, and in fact, can cause psychological harm.

   b. Specifically for positive test results, this could involve instituting treatments or surveillance measures, making decisions concerning future conception, or avoiding harmful treatments.

   c. Negative test results can have clinical utility in that unnecessary treatments or surveillance can be avoided.

B. Oncologic Genetic testing is covered (subject to Limitations/Exclusions and Administrative Guidelines) when the following criteria are met:

1. A positive or negative test will influence treatment decisions, course of treatment or medical management of the patient; or

2. Patient has a cancer or strong suspicion of cancer for the following conditions:

   a. Acute myeloid leukemia
   b. Acute promyelocytic leukemia
   c. Chronic lymphocytic leukemia
   d. Ewing's sarcoma
   e. Medullary thyroid carcinoma
   f. Multiple Myeloma
   g. Myelodysplastic syndrome
h. Myeloproliferative neoplasms
i. Non-Hodgkin's lymphoma
j. Non-small cell lung cancer
k. Retinoblastoma
l. Small lymphocytic lymphoma
m. Wilms tumor
n. Breast cancer (see section below for additional criteria)
o. Lynch Syndrome / Colorectal Cancer (see Lynch Syndrome policy)

3. A pre-test genetic risk assessment by a properly certified genetic specialist (requiring prior authorization) has been performed and is concurrent with the test request.
   a. Certified genetic specialists are:
      i. Board-certified medical geneticist (MD)
      ii. Board-certified clinical geneticist (PhD)
      iii. Board-certified genetic counselor (MS and/or CGC)
      iv. Licensed advanced practice registered nurse in genetics (APRN)

C. Breast cancer gene expression assay (i.e., Oncotype DX, EndoPredict, the Breast Cancer Index, Prosigna) is considered medically appropriate if ALL of the following are met:
   1. Newly diagnosed carcinoma of breast and ALL of the following:
      a. Primary, invasive breast cancer in women
      b. Unilateral tumor
      c. ANY ONE of the following:
         i. When 21-gene RT-PCR assay is NOT used, individual must be node negative (lymph nodes with micrometastases [less than 2 mm in size] are considered node negative)
         ii. When 21-gene RT-PCR assay is used, individual may be ANY ONE of the following:
            - Node negative (lymph nodes with micrometastases [less than 2 mm in size] are considered node negative)
            - Node positive (up to three positive axillary nodes in a post-menopausal woman)
         iii. Estrogen receptor positive or progesterone receptor positive
         iv. Human epidermal growth factor receptor 2 (HER2) negative
         v. Tumor size is ONE of the following:
            - 0.6 to 1 cm with moderate or poor differentiation
            - 0.6 to 1 cm with ONE of the following:
              o Angiolympathic invasion
              o High histologic grade
              o High nuclear grade
            - Larger than 1 cm
2. Individual will receive adjuvant endocrine therapy (e.g., tamoxifen, aromatase inhibitors)

3. Test is ordered within six months of diagnosis

4. Outcome of testing will guide decision-making regarding adjuvant chemotherapy

D. Within the limitations above, genetic testing is covered for National Comprehensive Cancer Network level 1 or 2A recommended tests.

E. EGFR, KRAS, and BRAF testing is covered (subject to limitations/Administrative Guidelines) in treatment planning of molecular targeted colon cancer therapy.

F. EGFR and KRAS testing is covered (subject to Limitations/Administrative Guidelines) in treatment planning of molecular targeted lung cancer therapy.

G. Gene expression assays for determining the prognosis of stage II or III colon cancer following surgery are not covered as they are not known to be effective in improving health outcomes.

NOTE:

This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.

III. Limitations/Exclusions

A. Genetic testing is not covered for the following:
   1. Family members of subscribers, who themselves are not subscribers, are not covered;
   2. Members are not covered if the results of the genetic testing are for the benefit of family members who are not covered by UHA;
   3. Genetic testing is not covered in the absence of associated signs, symptoms or complaints;
   4. Home Genetic testing is not covered
   5. Chemoresistance and chemosensitivity; (e.g., ChemoFx) are not covered.
   6. UGT1A1 Molecular Assay (Invader) are not covered;
   7. Pathfinder (Genetic fingerprinting/DNA fingerprinting) and any other genetic expressing test not supported by NCCN are not covered;
   8. Detection of circulating tumor cells in the management of patients with cancer is not covered.

B. Genetic testing for cancer susceptibility using panels of genes (with or without next generation sequencing) is not covered because it is not known to be effective in improving health outcomes. However, individual components of a panel may be considered medically necessary as noted in this policy.

C. For a known deleterious mutation, UHA will only cover a targeted single site analysis genetic test not a full analysis (i.e., testing for the mutation that has been identified in the family).
D. Most genetic tests are performed once per lifetime but neuro-oncologic therapies may warrant repeat testing and coverage based on current national clinical practices and guidelines.

E. Laboratories that conduct genetic testing must be CLIA certified.

F. Because of the rapidly evolving field of genetic testing, this policy does not address every genetic test available. All other conditions not mentioned in this policy will be reviewed based on medical necessity and the policy criteria.

### IV. Administrative Guidelines

A. Prior authorization is required for the necessary pre-test genetic risk assessment.

B. Prior authorization is required for genetic testing: oncology.

C. To request prior authorization, please go to UHA’s website: [https://uhahealth.com/page/prior-authorization-forms](https://uhahealth.com/page/prior-authorization-forms) and submit via UHA’s online portal.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>81206</td>
<td>BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative</td>
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<tr>
<td>81207</td>
<td>BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative</td>
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<td>81208</td>
<td>BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative</td>
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<tr>
<td>88230</td>
<td>Tissue culture for non-neoplastic disorders; lymphocyte</td>
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<tr>
<td>88233</td>
<td>Tissue culture for non-neoplastic disorders; skin or other solid tissue biopsy</td>
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<tr>
<td>88237</td>
<td>Tissue culture for neoplastic disorders; bone marrow, blood cells</td>
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<tr>
<td>88240</td>
<td>Cryopreservation, freezing and storage of cells, each cell line</td>
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<tr>
<td>88241</td>
<td>Thawing and expansion of frozen cells, each aliquot</td>
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<tr>
<td>88245</td>
<td>Chromosome analysis for breakage syndromes; baseline Sister Chromatid Exchange (SCE), 20-25 cells</td>
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<tr>
<td>88248</td>
<td>Chromosome analysis for breakage syndromes; baseline breakage, score 50-100 cells, count 20 cells, 2 karyotypes (e.g., for ataxia telangiectasia, Fanconi anemia, fragile X)</td>
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<tr>
<td>88249</td>
<td>Chromosome analysis for breakage syndromes; score 100 cells, clastogen stress (e.g., diepoxybutane, mitomycin C, ionizing radiation, UV radiation)</td>
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<tr>
<td>88261</td>
<td>Chromosome analysis; count 5 cells, 1 karyotype, with banding</td>
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<td>88262</td>
<td>Chromosome analysis; count 15-20 cells, 2 karyotypes, with banding</td>
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<tr>
<td>88263</td>
<td>Chromosome analysis; count 45 cells for mosaicism, 2 karyotypes, with banding</td>
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<tr>
<td>88264</td>
<td>Chromosome analysis; analyze 20-25 cells</td>
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<tr>
<td>88271</td>
<td>Molecular cytogenetics; DNA probe, each (e.g., FISH)</td>
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<td>88272</td>
<td>Molecular cytogenetics; chromosomal in situ hybridization, analyze 3-5 cells (e.g., for derivatives and markers)</td>
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<td>88273</td>
<td>Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (e.g., for microdeletions)</td>
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<td>88274</td>
<td>Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells</td>
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<td>88275</td>
<td>Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells</td>
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<tr>
<td>88280</td>
<td>Chromosome analysis; additional karyotypes, each study</td>
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<td>88283</td>
<td>Chromosome analysis; additional specialized banding technique (e.g., NOR, C-banding)</td>
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<td>88285</td>
<td>Chromosome analysis; additional cells counted, each study</td>
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<td>88289</td>
<td>Chromosome analysis; additional high resolution study</td>
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<td>88291</td>
<td>Cytogenetics and molecular cytogenetics, interpretation and report</td>
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<tr>
<td>S3840</td>
<td>DNA analysis for germline mutations of the RET proto-oncogene for susceptibility to multiple...</td>
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endocrine neoplasia type 2
S3841 Genetic testing for retinoblastoma

V. **Policy History**

- **Policy Number**: MPP-0058-120301
- **Current Effective Date**: 06/12/2018
- **Original Document Effective Date**: 03/01/2012, 02/12/2018
- **Previous Revision Dates**: 03/01/2012
- **PAP Approved Date**: 03/01/2012