Changes in Tumor Profile Testing for Members with Advanced Cancer Policy

Effective December 1, 2021, our Tumor Profile Testing for Members with Advanced Cancer policy will be updated. Please see attached policy for changes in:

- **Liquid biopsy (circulating tumor DNA, ctDNA) molecular profiling tests**
  Change in clinical criteria when testing by:
  - Plasma-based, somatic comprehensive genomic profiling test (CGP)
  - Plasma-based Next generation sequencing (NGS) assays performed on solid tumor cell free DNA in plasma

Tumor Profile Testing for Members with Advanced Cancer

DESCRIPTION

Cancer is the result of genetic changes to deoxyribonucleic acid (DNA) that can be inherited or acquired over a lifetime. While each cancer may have unique genetic changes that could vary among cells of the same tumor type, there are certain mutations that commonly cause cancer, including mutations to tumor suppressor genes, DNA repair genes, or proto-oncogenes.[1]

Tumor Profile testing also known as molecular profiling or comprehensive genomic profiling is a method for identifying multiple biomarkers in the malignant tumors of persons who have cancer. The biomarker information can be used to identify treatment options by classifying tumors based on the genetic make-up of the actual tumor. Using a sample obtained from either a tissue biopsy or from a liquid biopsy (typically blood), this testing examines the DNA of cancer cells, looking for genetic mutations or other biomarkers that have been acquired by these cells[2].

- Types of Biopsy:
  - **Tissue biopsy** - A tissue biopsy is the removal of tissue from any part of the body to examine it for disease. Some may remove a small tissue sample with a needle while others may surgically remove a suspicious nodule or lump.
  - **Liquid biopsy** - Usually performed on blood, liquid biopsies analyze DNA from whole circulating tumor cells (CTCs) or cell-free DNA (cfDNA) from tumors. Many tests specifically target a type of cfDNA called circulating tumor DNA (ctDNA), most of which comes from cells in the bed of the tumors.
- Technologies or lab procedures used in tumor profiling may include:
  - **Next-generation sequencing (NGS)** – Finds mutations in 5 to 500+ genes in a single test.
  - **Chromosomal microarray (CMA)** – Uses microchip-based test for high-volume, automated analysis of many pieces of DNA at once.
  - **Fluorescence in-situ hybridization (FISH)** – Locates a specific DNA sequence by exposing chromosomes to a DNA "probe" that has a fluorescent molecule attached to it.
  - **Polymerase chain reaction (PCR)** – Lets researchers "amplify" (produce millions of copies of) a DNA sequence fast and economically.
  - **Immunohistochemical studies (IHC)** – Uses staining to show whether or not the cancer cells have HER2 receptors and/or hormone receptors on their surface.
- Types of Tumor profile tests:
  - **Targeted Tumor Panels**: Targeted Next-Generation Sequencing (NGS) panels are defined as tests that identify somatic alterations known to occur in certain regions (i.e., 'hotspots') within specific genes of interest for cancer management (i.e., diagnosis, selection of molecularly targeted therapies, prognosis in a context where prognostic classification is essential for treatment selection). These alterations typically represent response or lack of response to corresponding targeted cancer therapies. The hotspot test should include relevant regions in the genes required for companion diagnostic testing and/or known to be necessary for proper patient management.
    - To bill for targeted NGS services, review CPT codes 81445, 81450 and 81455. Base the selected code on the number of genes in your laboratory's NGS panel and the test indication for solid organ or hematolymphoid neoplasms. The UOS for the NGS panel is one.
    - NOTE: Individual gene tests performed in the NGS panel should NOT be registered and reported with multiple CPT Tier 1 and/or Tier II codes
  - **Comprehensive Genomic Profile (CGP) Testing**: CGP refers to NGS-based molecular assays that provide additional insight beyond individual gene hotspots; these assays seek to describe the genomic makeup of a tumor and can help identify underlying mechanisms of disease to guide clinical decision making. These tests include not only mutations in individual relevant genes, but also patterns of mutations across related genes in established cancer pathways and often include an assessment of overall mutational burden. These tests typically involve sequencing of entire exonic regions of genes of interest (within a comprehensive gene panel or whole exome sequencing), and may also include selected intronic regions. CGP can detect multiple types of molecular alterations (i.e., SNVs, small and large INDELs, copy number alterations (CNAs), structural variants (SVs), and splice-site variants) in a single assay. Patterns of mutations seen across multiple genes may be used to infer clinically relevant etiologies, such as DNA mismatch repair deficiency and microsatellite instability, and total mutational load/burden (TMB) may be determined. CGP testing may also include RNA sequencing to detect structural variations, such as translocations or large deletions, and to detect functional splicing mutations. CGP is not defined as a targeted panel.
    - Because CGP includes SNVs, small (≤ 10 bp) and large (> 10 bp) insertions and deletions, CNVs, AND rearrangements (i.e., translocations/fusions), CPT codes 81445, 81450, and 81455 do NOT describe a CGP service. Therefore, to report a CGP service, test providers should use CPT code 81479.
  - **Liquid biopsy (circulating tumor DNA, ctDNA) molecular profiling tests**: Traditionally testing is performed on tumor samples. This requires the availability of adequate tumor tissue. A liquid biopsy is used to test the Member's blood for evidence of actionable mutations coming from the tumor. NOTE: Tissue-based testing remains the preferred tool to test for actionable mutations in cancer. When obtaining tumor tissue is not feasible, liquid biopsy technology represents an alternative which may allow more Members to receive potentially effective cancer treatment.

This policy addresses tumor profiling or somatic testing of cancer cells. Germline testing is performed on healthy cells to assess for risks to develop cancer. Germline testing may be found in Benefit Administration Manual policies such as: Genetic Testing for Heritable Conditions or Tumor Markers for Cancer.

RELEVANT CODES

81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81479	Unlisted Molecular Pathology Procedure

COVERAGE CRITERIA

Tissue biopsy molecular profiling testing:

Molecular profiling performed using tumor tissue using either Targeted Next-Generation Sequencing (NGS) panels or Comprehensive Genomic Profile (CGP) Testing (not cell-free circulating tumor DNA, also known as liquid biopsy) is covered when the following are met:

1. **Clinical criteria** : HAP/AHL Members who have coverage for genetic testing when ALL the following are met:
   a. Member has recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer;
   b. ONE of the following is met:
      i. Member has not been previously tested using the same NGS test for the same primary diagnosis of cancer,
      ii. Request for repeat testing using the same NGS test is covered only when a new primary cancer diagnosis is made by the treating physician
   c. Member has decided to seek further cancer treatment (e.g., therapeutic chemotherapy).
2. **Test criteria:** FDA approved or cleared in vitro companion diagnostic laboratory tests using Next Generation Sequencing (NGS) may be covered as a diagnostic laboratory test when:
   a. Performed in a CLIA-certified laboratory, when ordered by a treating physician, clinical criteria are met, the Member has coverage for genetic testing, and ALL the following requirements are met:
      i. Food & Drug Administration (FDA) approval or clearance as a companion in vitro diagnostic
      ii. Test is an FDA-approved or -cleared indication for use in the Member's cancer
      iii. Test results will be provided to the treating physician for management of the Member's care using a report template to specify treatment options.
      iv. The test has satisfactorily completed a Technical Assessment by MolDX for the stated indications of the test
      v. The assay performed includes at least the minimum genes and genomic positions required for the identification of clinically relevant FDA-approved therapies with a companion diagnostic biomarker as well as other biomarkers known to be necessary for clinical decision making for its intended use that can be reasonably detected by the test.

b. Please refer to the Benefit Administration Manual policy: Pharmacogenetic/Pharmacogenomic and Companion Diagnostic Testing for additional coverage of a specific test.
c. Pre-authorization requirements apply.
    i. ALL tests not performed by a preferred HAP-contracted laboratory must be prior authorized.

Liquid biopsy (circulating tumor DNA, ctDNA) molecular profiling tests:
Liquid biopsy (circulating tumor DNA, ctDNA) molecular profiling tests (also known as blood-based comprehensive somatic genomic profile testing or CGP) which has been demonstrated as consistent with MolDX's Analytical Performance Specifications for Qualitative Tumor-only Somatic Variant Detection using Circulating Tumor DNA (M00135) may be covered as follows:

1. **Clinical Criteria for testing by**:
    a. Plasma-based, somatic comprehensive genomic profiling test (CGP)[such as Inivata, InVisionFirst, Liquid Biopsy]:
        i. **Medicare product Members** who have advanced (Stage IIIB/IV) non-small cell lung cancer (NSCLC) are covered for one CGP testing at either the time of diagnosis OR later if cancer is progressing.
            A. Testing at diagnosis is covered when BOTH the following are met:
                I. Results for EGFR single nucleotide variants (SNVs) and insertions and deletions (indels); rearrangements in ALK and ROS1; and SNVs for BRAF are not available
                II. Tissue-based CGP is infeasible [i.e., quantity not sufficient (QNS) for tissue-based CGP or invasive biopsy is medically contraindicated]
            B. Testing at progression is covered when EITHER of the following are met:
                I. Member's cancer is progressing during or after chemotherapy or immunotherapy who have not been tested for EGFR SNVs and indels; rearrangements in ALK and ROS1; and SNVs for BRAFs, and for whom tissue-based CGP is infeasible;
                II. Member's cancer is progressing on EGFR tyrosine kinase inhibitors (TKIs)
        ii. **Members other than Medicare Members** who have non-small cell lung cancer (NSCLC) and have coverage for Genetic testing are covered for CGP testing when BOTH the following are met:
            A. One test at either the time of diagnosis OR later if cancer is progressing.
            B. Tissue-based CGP is infeasible [i.e., quantity not sufficient (QNS) for tissue-based CGP or invasive biopsy is medically contraindicated]
    b. Plasma-based next generation sequencing (NGS) assays performed on solid tumor cell free DNA in plasma [such as Guardant360®]:
        i. **Medicare product Members** are covered for testing when ALL the following are met:
            A. Member has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced solid tumor that did not originate from the central nervous system.
                I. NOTE: Members who would meet all of the indications on the Food and Drug Administration (FDA) label for larotrectinib if they are found to have a neurotrophic receptor tyrosine kinase (NTRK) mutation may be considered to have advanced cancer.
            B. Member has not previously been tested with the same test (such as Guardant360®) for the same genetic content.
            C. Member is untreated for the cancer being tested or the Member is not responding to treatment (e.g. progression or new lesions on treatment)
            D. Member has decided to seek further cancer treatment when BOTH the following are met:
                I. Member is a candidate for further treatment with a drug that is either FDA-approved for that Member's cancer, or has a National Comprehensive Cancer Network (NCCN) or NCCN 2A recommendation for that Member's cancer, and
                II. The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Guardant360® assay and
            E. Tissue-based, comprehensive genomic profiling (CGP) is infeasible (e.g., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) or specifically in NSLC Tissue-based CGP has shown no actionable mutations.
        ii. **Members other than Medicare Members** who have non-small cell lung cancer (NSCLC) and have coverage for Genetic testing are covered for Next generation sequencing (NGS) assays performed on solid tumor cell free DNA in plasma when BOTH the following are met:
            A. Member has not previously been tested with the same test (such as Guardant360®) for the same genetic content.
            B. Tissue-based, comprehensive genomic profiling (CGP) is infeasible (e.g., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) or specifically in NSLC Tissue-based CGP has shown no actionable mutations.
2. **Test criteria**: FDA approved or cleared diagnostic laboratory tests circulating tumor DNA molecular profiling may be covered as a diagnostic laboratory test when performed in a CLIA-certified laboratory, when ordered by a treating physician, Member criteria are met, and ALL the following requirements are met:
    a. ONE of the following are met:
        i. The diagnostic laboratory test meets coverage criteria as outlined on the Benefit Administration Manual policy: Pharmacogenetic/Pharmacogenomic and Companion Diagnostic Testing.
        ii. The test meets coverage guidelines as described above.
    b. Pre-authorization requirements apply for all testing.
        i. ALL tests not performed by a preferred HAP-contracted laboratory must be prior authorized.

FOR ALL ABOVE TESTING:

1. Coverage of services is based on the Member's subscriber documents. Please refer to those resources for information regarding eligibility for coverage, network or provider requirements. If the Member has coverage for the services discussed in this policy, then the medical criteria applies.
    a. Genetic testing is covered for HAP Members. Some AHL Members (non-Medicare Advantage Members & non-QHP Members) do not have coverage for tests which are classified as genetic tests.
2. HAP/AHL and QHP Members other than Medicare Advantage:
    a. Due to the lack of standardization of testing panels, HAP will preferentially cover equivalent panels that contain evidence-based genetic components when available from a HAP preferred provider. Genetic testing for Members with advanced cancer may be covered when obtained through HAP's preferred lab for genetic testing. Tests include but are not limited to:
        i. Comprehensive Solid Tumor Cancer Panel
        ii. Additional tests are available, please refer to:
            A. Henry Ford Center for Precision Diagnostics. Precision Genomic Testing Services.
            http://pathology.hfhs.org/Flipbooks/HFCPD%20flipbook/flipbook/index.html?page=1
3. Medicare Advantage Plan Members are covered in accordance with applicable Medicare National Coverage Determination (NCD) or by Local Coverage Determinations in addition to qualifying for tests available through HAP's preferred lab for genetic testing.
    a. Liquid Biopsy testing addressed by LCD at time of the review include:
        i. InvisionFirst™ - Lung (Inivata)
        ii. Guardant 360
4. Members with Medicare-Medicaid products or dual coverage products are covered under the Medicare component using the same criteria as Medicare Advantage Plan Members.
5. Medicaid Providers should refer to:
    a. The Michigan Medicaid Fee Schedule located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html**

LIMITATIONS

1. **Companion In vitro companion diagnostic laboratory tests:** Comprehensive Genomic Profile (CGP) Testing: Coverage of CGP is limited to one test per surgical specimen and precludes the use of any other molecular testing on that specimen.
2. **Liquid biopsy tests:**
    a. If no alteration is detected by approved testing or if ctDNA is insufficient/not detected, tissue-based genotyping should be considered.
    b. Use for non-CNS solid tumors: Liquid biopsy refers to serum testing for DNA fragments that are shed by cancer cells and released into the bloodstream. Liquid biopsy testing is currently not used for CNS tumors because they are uncommon (limiting opportunity for research) and the discovery of blood-based tumor markers is impaired by the existence of the Blood-Brain Barrier. Research is on-going but testing at the time of this policy has not yet been able to successfully and accurately utilize blood-based tumor markers suitable for clinical practice.

EXCLUSIONS

1. **Members other than Medicare Advantage Plan Members**: Due to the lack of standardization of genetic tests, genetic testing panels and genomic profile testing, HAP may cover equivalent tests, test panels, or genomic profile tests when available from a HAP preferred provider. Genetic testing utilizing a non-preferred HAP provider is not covered when a comparable test, testing panel, or genomic profile test is available in plan.
2. Members who do not have coverage for Genetic testing based on the Member-specific subscriber documents, are not covered.

3. Companion Diagnostic laboratory tests:
    a. Genomic profile tests that are not identified by the FDA as an approved companion test for the Member's cancer are not covered by this policy.
    b. Testing is not covered if another CGP test was performed on the same tumor specimen (obtained on same date of service)
4. Non-Covered tests for Commercial, QHP (non-Medicare Advantage Members) unless otherwise specified: Each of the following tests have a comparable test, testing panel, or genomic profile test available in plan and are not covered. List may not be all-inclusive. [Note: Coverage for Medicare Advantage Members follows the NCD/LCD if available]:
    a. Tempus genomic panel testing for all indications.
    b. Caris Target Now Molecular Profiling Test/ Caris Molecular Intelligence tests
5. HAP follows Medicare billing guidelines for all Members: Genetic testing is not covered when Medicare billing rules are not followed.
    a. Local Coverage Article: MolDX: Targeted and Comprehensive Genomic Profile Next Generation Sequencing (NGS) Testing in Cancer (A55197) provides coding instructions for targeted tumor profiles and comprehensive genomic profile (CGM) testing. For targeted tumor profiling panel for somatic variant detection, 81445 or 81450 (UOS=1) must be submitted. For comprehensive genomic profiling providers should use CPT code 81479 with the appropriate DEX Z code. The LCA clarifies appropriate CPT coding and removed CPT 81455. Individual biomarker CPT codes should not be used for a single gene or any combination of genes when testing is performed as part of tumor profiling panel or other multiplatform panel. The service provider must correct the coding error as required by CMS.

Medicaid Providers should refer to the Michigan Medicaid Fee Schedule located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.htm**

RELATED BENEFIT ADMINISTRATION MANUAL POLICIES:

1. Pharmacogenetic-Pharmacogenomic and Companion Diagnostic Testing
2. Circulating Tumor Cells Testing using the CellSearch System ™ for Medicare Advantage Members only
3. Gene-Based Testing for Prostate Cancer Screening, Detection and Disease Monitoring
4. Genetic Expression Assays for Breast Cancer Prognosis
5. Genetic Testing at HAP
6. Genetic Test Panels
7. Tumor Markers for Cancer

REFERENCES:

HAP Preferred lab for Genetic testing:
Henry Ford Center for Precision Diagnostics. Commonly Ordered CPT and Test Codes Chart. **https://www.henryford.com/hcp/academic/pathology/precision-diagnostics/commonly-ordered-cpt-and-test-codes**

MEDICARE REFERENCE:

1. Decision Memo for NEXT GENERATION Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N) **https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=290&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=B**
    a. Per the Decision Memo for NEXT GENERATION Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N), a list of FDA cleared or approved companion diagnostic in vitro devices using NGS is currently available at **https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm**.
2. Erlanger Health System Foundation. Molecular Profiling (Genomic Testing), Studying the DNA of cancer to tailor treatments and improve outcomes. Chattanooga, TN. **https://www.erlanger.org/centers-of-excellence/cancer-services/cancer-services/molecular-profiling**
3. Decision Memo for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450R) **https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=296**
4. US Food & Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Avail @ **https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/ucm301431.htm**
5. CGS Medicare. Next Generation Sequencing Coding and Billing Guidelines (CM00097). April 7, 2016. **https://www.cgsmedicare.com/articles/cope32486.html**
6. **Covered Diagnosis codes**: CMS Manual System. Department of Health & Human Services (DHHS). National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS). Pub 100-03 Medicare National Coverage Determinations. Centers for Medicare & Medicaid Services (CMS), Transmittal 210, Date: November 30, 2018. Change Request 10878. **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R210NCD.pdf**
7. MLN Matters. National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS). MLN Matters Number: MM10878. Related CR Release Date: November 30, 2018. Related CR Transmittal Number: R210NCD. Related Change Request (CR) Number: 10878. Effective Date: March 16, 2018. Implementation Date: March 8, 2019 -A/B MACs. **https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10878.pdf**
8. **National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2) https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372&ncdver=1&DocID=90.2&bc=gAAAABAAAAAA&**
9. **Local Coverage Determination (LCD): MolDX: Next-Generation Sequencing for Solid Tumors (L38158) https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38158**
    a. Local Coverage Article: Billing and Coding: MolDX: **Next-Generation Sequencing for Solid Tumors (A57858) https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57858&ver=4&LCDId=38158&bc=AAAAAAAAEAAAAAAA&**
    b. Local Coverage Article:
    MolDX: **Targeted and Comprehensive Genomic Profile Next Generation Sequencing Testing in Cancer (A55197)**
    https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55197&ver=18&Date=10%2f20%2f2019&DocID=A55197&SearchType=Advanced&bc=JAAAABAAkAAAAAAA&=
10. Local Coverage Determination (LCD): MolDX: **Inivata, InVisionFirst**, Liquid Biopsy for Patients with Lung Cancer (L37921)
    https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37921
    a. Local Coverage Article:
    Billing and Coding: **MolDX: Inivata, InVisionFirst, Liquid Biopsy** for Patients with Lung Cancer (A56333)
    https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56333&ver=7&LCDId=37921&bc=AAAAAAABEAAA&
11. **LIQUID BIOPSY: Solid Tumors**
    a. Local Coverage Determination (LCD):
    MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38168)
    https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38168
        i. Local Coverage Article: Billing and Coding: MolDX: **Plasma-Based Genomic Profiling in Solid Tumors (A57936) https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57936**
        ii. **LIQUID BIOPSY: Lung Cancer**
            a. RETIRED Local Coverage Determination (LCD):
            MolDX: **Guardant360®** Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer (NSCLC) (L37671)
            https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=37671%3a9

This Benefit policy discusses the medical criteria for covered services. Coverage of services for Members is based on the Member's subscriber documents and are subject to all terms and conditions including specific exclusions and limitations. This type of document includes the following: Subscriber contract and associated riders; Member Benefit Guide; or an Evidence of Coverage document (for Medicare Advantage Members).
HAP HMO/POS and AHL EPO/PPO Members:
If there is a discrepancy between this policy and coverage described in the subscriber documents, the Member's subscriber documents will apply.
ASO Members:
Coverage as discussed in this policy may not apply to employer groups that are self-funded (referred to as an ASO group [Administrative Services Only]). Each ASO group determines the coverage available to their members which is found in the ASO Benefit Guide and associated riders. If a member has coverage for the type of service covered by this policy, then the medical criteria as discussed in this policy applies to those services.
Medicare Advantage Plan Members:
Coverage is based on Medicare (CMS) regulations and guidelines which include the NCDs (National Coverage Decision) and LCDs (Local Coverage Decision) for our area. When no coverage determination has been made by CMS, then this policy will apply.
Medicaid Plan Members:
For Medicaid/Healthy Michigan Plan members coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on

the Michigan Medicaid Fee Schedule located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html**. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: **http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html**, the Michigan Medicaid Provider Manual will apply.

EFFECTIVE DATE

12/01/2018

REVISED DATE

09/10/2021

REVIEWED DATE

02/13/2020