

## Medical Policy updates – 11/1/2023

### MEDICAL, BEHAVIORAL HEALTH, DURABLE MEDICAL EQUIPMENT (DME) & MEDICAL DENTAL COVERAGE POLICY

Please read this list of new or revised HealthPartners coverage policies. HealthPartners coverage policies and related lists are available online at [healthpartners.com](https://www.healthpartners.com). Upon request, a paper version of revised and new policies can be mailed to clinic groups whose staff does not have Internet access. Providers may speak with a HealthPartners Medical Director if they have a question about a utilization management decision.

Coverage Policies	Comments / Changes
<p>Surgical treatment of gender dysphoria</p> <p>Gender-affirming surgery – Minnesota Health Care Programs</p>	<p>Effective 12/1/2023 prior authorization is no longer required for hysterectomy or salpingo-oophorectomy for treatment of gender dysphoria. These procedures are eligible for coverage subject to any specific plan limitations.</p>
<p>Genetic testing: gastroenterologic disorders (non-cancerous)</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Coverage requirements for <b>Hereditary Inflammatory Bowel Disease/Crohn’s Disease Panel Tests</b> have been updated to include clinical features and age of onset. This section now reads as follows: <ul style="list-style-type: none"> <li>○ Genetic testing for hereditary inflammatory bowel disease, including Crohn’s disease, via a multigene panel is considered <b>medically necessary</b> when: <ul style="list-style-type: none"> <li>▪ The member had very early onset of IBD symptoms before age 2 years, <b>or</b></li> <li>▪ The member had IBD symptoms before age 18 years, <b>and</b> <ul style="list-style-type: none"> <li>• At least one of the following: <ul style="list-style-type: none"> <li>❖ Affected family member with a suspected monogenic disorder, who has not had genetic testing, <b>or</b></li> <li>❖ Multiple family members with early-onset IBD, <b>or</b></li> <li>❖ Consanguinity, <b>or</b></li> <li>❖ Recurrent infections, <b>or</b></li> <li>❖ Hemophagocytic lymphohistiocytosis (HLH), <b>or</b></li> <li>❖ Autoimmune features, <b>or</b></li> <li>❖ Autoimmune and dermatological features, <b>or</b></li> <li>❖ Malignancy, <b>or</b></li> <li>❖ Multiple intestinal atresias.</li> </ul> </li> </ul> </li> <li>○ Genetic testing for inflammatory bowel disease, including Crohn’s disease, via a multigene panel is considered <b>investigational</b> for all other indications. <ul style="list-style-type: none"> <li>▪ Prior authorization continues to be required for this service.</li> </ul> </li> </ul> </li> <li>• <b>Hereditary Hemochromatosis/HFE C282Y and/or H63D Genotyping</b> section: clinical criteria name changed (formerly called “HFE Sequencing and/or Deletion/Duplication Analysis”). <ul style="list-style-type: none"> <li>○ Prior authorization requirements for Hereditary Hemochromatosis testing have not changed.</li> </ul> </li> </ul> </li></ul>

Coverage Policies	Comments / Changes
<p>Genetic testing: exome and genome sequencing for the diagnosis of genetic disorders</p> <p>(commercial and MHCP versions)</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• <b>Standard Exome Sequencing</b> criteria have been updated. <ul style="list-style-type: none"> <li>○ Added requirement that member has not previously undergone whole genome sequencing.</li> <li>○ Repeat standard exome sequencing no longer considered medically necessary in light of the update to cover genome sequencing when criteria are met; see Standard Genome Sequencing criteria section.</li> </ul> </li> <li>• <b>Reanalysis of Whole Exome Sequencing Data</b> <ul style="list-style-type: none"> <li>○ New criteria section</li> <li>○ Reanalysis of whole exome sequencing data is considered medically necessary when criteria are met.</li> </ul> </li> <li>• <b>Standard Genome Sequencing</b> <ul style="list-style-type: none"> <li>○ Changed coverage stance from investigational to medically necessary when criteria are met.</li> </ul> </li> <li>• Please refer to published coverage policy for details</li> <li>• Prior authorization continues to be required for exome and genome sequencing for the diagnosis of genetic disorders.</li> <li>• Please note, these changes also apply to the Minnesota Health Care Providers (MHCP) version of this policy, with the exception of the Rapid Genome Sequencing section. That section reflects MHCP provider manual criteria and has not been revised.</li> </ul>
<p>Genetic testing: general approach to genetic testing (<i>renamed "Genetic testing: general approach to genetic and molecular testing"</i>)</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• <b>General Tumor Biomarker Analysis</b> <ul style="list-style-type: none"> <li>○ New criteria section. This section adds clinical criteria to provide guidance on the review of tests for tumor biomarker analysis when specific criteria have not yet been developed.</li> </ul> </li> <li>• <b>Oncology Algorithmic Tests</b> <ul style="list-style-type: none"> <li>○ New criteria section. This section adds clinical criteria to provide guidance on the review of tests for tumor algorithmic testing when specific criteria have not yet been developed.</li> </ul> </li> <li>• <b>Other Tests</b> <ul style="list-style-type: none"> <li>○ New criteria section. This section adds clinical criteria to direct reviewers and provide guidance on the review of tests for non-genetic, non-oncology testing when specific criteria have not yet been developed.</li> </ul> </li> <li>• Newly added sections require that the chosen test has clinical utility, as demonstrated by meeting criteria outlined in the policy. Please refer to published coverage policy for details.</li> <li>• Prior authorization continues to be required for genetic testing unless otherwise indicated in another coverage policy.</li> </ul>

Coverage Policies	Comments / Changes
<p>Genetic testing: multisystem inherited disorders, intellectual disability and developmental delay</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• <b>Angelman/Prader-Willi Syndrome/SNRPN/UBE3A Methylation Analysis, 15q11-q13 FISH Analysis, Chromosome 15 Uniparental Disomy Analysis, and Imprinting Center Defect Analysis:</b> criteria revised (specifically, the age at which features would meet clinical criteria changed from birth to one month).</li> <li>• <b>Cystic Fibrosis/CFTR Sequencing and/or Deletion/Duplication Analysis:</b> criteria revised to remove the unexplained acute recurrent pancreatitis/chronic pancreatitis criteria point, consistent with current guidelines.</li> <li>• <b>Noonan Spectrum Disorders/RASopathies Multigene Panel:</b> addition of <i>SPRED1</i> to minimum gene list and <b>removal of Legius Syndrome</b> (caused by germline mutations in <i>SPRED1</i>) as a stand-alone test as <i>SPRED1</i> is in the RAS pathway (thus a RASopathy) and has overlapping clinical features with Noonan syndrome and other RASopathies.</li> <li>• <b>New criteria section: NF2-Related Schwannomatosis (previously known as Neurofibromatosis 2)/NF2 Sequencing and/or Deletion/Duplication Analysis:</b> criteria name change due to categorization of Neurofibromatosis criteria into separate criteria sets that are clinically distinct (formerly called “Neurofibromatosis”) (<i>NF1</i> or <i>NF2</i> Sequencing and/or Deletion/Duplication Analysis), and criteria revised to include a separate section for the diagnosis of children, consistent with expert authored guidelines.</li> <li>• <b>Replaced criteria: Neurofibromatosis:</b> refer to Neurofibromatosis 1 – <i>NF1</i> Sequencing and/or Deletion/Duplication Analysis; and/or <i>NF2</i>-Related Schwannomatosis (previously known as Neurofibromatosis 2) – <i>NF2</i> Sequencing and/or Deletion/Duplication Analysis.</li> <li>• <b>Replaced criteria: Legius Syndrome/SPRED1:</b> refer to Noonan Spectrum Disorders/RASopathies Multigene Panel test.</li> <li>• <b>Chromosomal Microarray Analysis for Developmental Delay/Intellectual Disability, Autism Spectrum Disorder, or Congenital Anomalies:</b> criteria section name changed (formerly called “Chromosomal Microarray Analysis”) and revised criteria based on updated literature to include short stature as an indication for testing.</li> <li>• <b>Autism Spectrum Disorder/Intellectual Disability Panel Analysis:</b> criteria section name changed (formerly called Developmental Delay/intellectual Disability, Autism Spectrum Disorder or Congenital Anomalies).</li> <li>• <b>Rett syndrome/MECP2 Sequencing and Deletion/Duplication Analysis:</b> moved criteria to the Epilepsy, Neurodegenerative and Neuromuscular Disorders policy.</li> <li>• <b>CADASIL/NOTCH3 Sequencing and/or Duplication Analysis:</b> moved criteria to the Epilepsy, Neurodegenerative and Neuromuscular Disorders policy.</li> <li>• <b>Charge Syndrome/CHD7 Sequencing and/or Deletion/Duplication Analysis:</b> criteria revised to better align with professional guidelines.</li> <li>• <b>Tuberous Sclerosis Complex (TSC)/TSC1 and TSC2 Sequencing and/or Deletion Duplication Analysis:</b> criteria revised to better align with professional guidelines.</li> <li>• <b>PIK3CA-Related Overgrowth Spectrum:</b> criteria section name changed (formerly called “PIK3CA-Related Segmental Overgrowth and Related Syndromes”) and criteria revised to reflect current recommendations. <ul style="list-style-type: none"> <li>○ Please refer to published coverage policy for details.</li> <li>○ Prior authorization requirements have not changed for this policy.</li> </ul> </li> </ul>

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<p>Genetic testing: epilepsy, neurodegenerative, and neuromuscular disorders</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• <b>Comprehensive Neuromuscular Disorders:</b> multiple revisions to this criteria section to be consistent with guidelines.</li> <li>• <b>Rett Syndrome:</b> criteria moved to this policy from the Multisystem <b>Inherited Disorders, Intellectual Disability, and Developmental Delay</b> policy.</li> <li>• <b>CADASIL:</b> criteria moved to this policy from the Multisystem <b>Inherited Disorders, Intellectual Disability and Developmental Delay</b> policy, and updated so that member is eligible when criteria in Section B or C are met.</li> <li>• <b>Alzheimer Disease – PSEN1, PSEN2, and APP Sequencing and/or Deletion/Duplication Analysis:</b> removed multigene panel from title of coverage criteria and added that testing via other genes is considered investigational.</li> <li>• <b>Alzheimer Disease – APOE Variant Analysis for Alzheimer’s Disease:</b> updated criteria to include a path to coverage based on FDA prescribing information for newly approved drug Leqembi.</li> <li>• <b>Alzheimer Disease – APOE, TREM2 and Other Variant Analysis:</b> section is replaced by updated sections ‘APOE Variant Analysis for Alzheimer’s Disease (APOE testing)’ and ‘PSEN1, PSEN2, and APP Sequencing and/or Deletion/Duplication Analysis’.</li> <li>• <b>Duchenne and Becker Muscular Dystrophy:</b> criteria clarified to be consistent with guidelines and clinical practice.</li> <li>• <b>Facioscapulohumeral Muscular Dystrophy (FSHD):</b> removed the requirement that member does not have a first-degree relative with a confirmed genetic diagnosis of FSHD.</li> <li>• <b>Friedreich’s Ataxia:</b> criteria revised to indicate member must have at least two clinical features from the list; additional features were added.</li> <li>• <b>Huntington’s Disease:</b> criteria revised to include testing recommendations developed by the Huntington’s Disease Society of America.</li> <li>• <b>Parkinson Disease:</b> Minimum gene list removed due to lack of clarity and established professional society guidelines in this clinical area. Coverage added for multigene panel testing when criteria are met.</li> <li>• <b>Congenital Myasthenic Syndrome:</b> multiple revisions to this criteria section to be consistent with guidelines.</li> <li>• <b>Myotonia Congenita:</b> removed requirement for elevated serum creatine kinase levels.</li> <li>• <b>Hypokalemic Periodic Paralysis:</b> added coverage for multigene panel testing for this condition.</li> <li>• <b>Hereditary Spastic Paraplegia:</b> removed minimum gene list to reflect available tests on the market.</li> <li>• <b>Other Covered Epilepsy, Neuromuscular, and Neurodegenerative Disorders:</b> added AADC deficiency to this list of conditions. <ul style="list-style-type: none"> <li>○ Please refer to published coverage policy for details.</li> <li>○ Prior authorization continues to be required for genetic testing for epilepsy, neurodegenerative and neuromuscular disorders.</li> </ul> </li> </ul>

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<p>Genetic testing: oncology - algorithmic testing  (commercial and MHCP versions)</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• <b>Breast Cancer Treatment and Prognostic Algorithmic Tests:</b> criteria revised to apply regardless of menopausal status. The Breast Cancer Index test was removed from this section; see new criteria section for extended endocrine therapy.</li> <li>• <b>New criteria. Breast Cancer Extended Endocrine Therapy Algorithmic Tests:</b> addition of new clinical criteria and new test category based on the intended use of the Breast Cancer Index test.</li> <li>• <b>Breast Cancer Prognostic Algorithmic Tests:</b> criteria revised to reflect ASCO guidelines for use based on menopausal status, age and node status.</li> <li>• <b>Prostate Cancer Treatment and Prognostic Algorithmic Tests:</b> addition of life expectancy and adverse pathologic feature requirements consistent with NCCN Guidelines.</li> <li>• <b>Combined criteria. Bladder/Urinary Tract Cancer Diagnostic, Treatment, and Recurrence Algorithmic Tests:</b> merging of clinical criteria (Urinary Tract Cancer Recurrence Algorithmic Tests) with Bladder Cancer Diagnostic and Recurrence Algorithmic Tests to reflect clinical practice and the types of tests available.</li> <li>• <b>Retired criteria. Multiple Myeloma Polygenic Risk Score Tests</b> as there are no tests currently available on the market.</li> <li>• <b>Oncology: Test-specific Not Covered Algorithmic Tests:</b> removal of example tests due to evidence that they are no longer available to be ordered. <ul style="list-style-type: none"> <li>○ Please refer to published coverage policy for details.</li> <li>○ Prior authorization requirements have not changed for this policy.</li> </ul> </li> <li>• Please note, these changes also apply to the Minnesota Health Care Providers (MHCP) version of this policy, with the exception of the following sections: <ul style="list-style-type: none"> <li>○ Breast Cancer Treatment and Prognostic Algorithmic Tests</li> <li>○ Breast Cancer Extended Endocrine Therapy Algorithmic Tests</li> <li>○ Breast Cancer Prognostic Algorithmic Tests</li> </ul> </li> <li>• These sections reflect MHCP provider manual criteria for Genetic Testing for Breast Cancer and have not been revised.</li> </ul>
<p>Eyewear – Minnesota Health Care Programs</p>	<p>Effective immediately, policy revised. Indications That Are Not Covered: updated policy language to reflect language in the MHCP provider manual.</p>
<p>Genetic testing: non-invasive prenatal screening (NIPS)</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Non-invasive Prenatal Screening (NIPS) for Chromosome 13, 18, and 21 Aneuploidies <ul style="list-style-type: none"> <li>○ Addition of one new indication: The member has not previously had cell-free DNA screening in the current pregnancy.</li> <li>○ Removal of one indication: The member has received appropriate counseling about the benefits and limitations of this test by a prenatal care provider, a trained designee or a genetic counselor.</li> <li>○ Prior authorization not required.</li> </ul> </li> </ul>

Coverage Policies	Comments / Changes
<p>Genetic testing: oncology – circulating tumor DNA and circulating tumor cells (liquid biopsy)</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Under broad molecular profiling panel tests via circulating tumor DNA: <ul style="list-style-type: none"> <li>○ Expanding the criterion indicating a member is to have a diagnosis of listed indications. Expansion of the criterion statement now indicates the member is to have a diagnosis, progression or recurrence of listed indications.</li> <li>○ Adding two indications that can lead to approval of this type of testing: <ul style="list-style-type: none"> <li>▪ The member has a diagnosis, progression or recurrence of advanced (stage III or higher) cutaneous melanoma.</li> <li>▪ The member has a diagnosis, progression or recurrence of hormone receptor positive/HER2-negative recurrent unresectable or stage IV breast cancer.</li> </ul> </li> <li>○ Removing one investigational indication: <ul style="list-style-type: none"> <li>▪ Broad molecular profiling panel tests via circulating tumor DNA (liquid biopsy) performed subsequent to solid tumor tissue testing are considered investigational.</li> </ul> </li> </ul> </li> <li>• Under lung cancer focused panel tests via circulating tumor DNA: <ul style="list-style-type: none"> <li>○ Expanding the criterion indicating a member is to have a diagnosis of listed indications. The criterion statement now indicates the member is to have a diagnosis or progression of listed indications.</li> </ul> </li> <li>• Under colorectal cancer focused panel tests via circulating tumor DNA: <ul style="list-style-type: none"> <li>○ A member is to have a diagnosis of metastatic colorectal adenocarcinoma to qualify once all other listed criteria are met.</li> <li>○ Expanding the criteria set by adding indications regarding biopsy completion.</li> </ul> </li> <li>• Moving melanoma focused panel tests via circulating tumor DNA away from being considered investigational to medically necessary when criteria are met for members with a diagnosis or recurrence of advanced (stage III or higher) cutaneous melanoma, when the panel includes BRAF and NRAS analysis, and when biopsy indications are met.</li> <li>• Reorganization of the BRAF variant analysis via circulating tumor DNA criteria section with clarification of indications regarding biopsy that need to be met to approve this modality of testing.</li> <li>• Reorganization of the KRAS variant analysis via circulating tumor DNA criteria section with clarification of indications regarding biopsy that need to be met to approve this modality of testing.</li> <li>• Under PIK3CA Variant Analysis via ctDNA: <ul style="list-style-type: none"> <li>○ Adding two indications that can lead to approval of this type of testing: <ul style="list-style-type: none"> <li>▪ The member is to be under consideration for treatment with alpelisib plus fulvestrant.</li> <li>▪ The member is to have had progression on at least one line of therapy.</li> </ul> </li> </ul> </li> <li>• Please refer to published coverage policy for details.</li> </ul>

Coverage Policies	Comments / Changes
Genetic testing: dermatologic conditions	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Under Epidermolysis Bullosa Multigene Panels: <ul style="list-style-type: none"> <li>○ Replace “may be” in “The member has the presence of blistering that may be present in the neonatal period” with “is” such that the indication reads as “The member has the presence of blistering that is present in the neonatal period” to establish presence of indication for testing.</li> <li>○ Replace “can lead” in “The member has the presence of blistering that can lead to progressive brown pigmentation interspersed with hypopigmented spots on the trunk and extremities” with “leads” such that the indication reads as “The member has the presence of blistering that leads to progressive brown pigmentation interspersed with hypopigmented spots on the trunk and extremities” to establish presence of indication for testing.</li> </ul> </li> </ul>
Genetic testing: skeletal dysplasia and rare bone disorders	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Addition of new criteria section: Multigene Panel Analysis for Skeletal Dysplasia or Rare Bone Disorder. Inclusion of coverage indications to warrant pursuing post-natal testing to confirm or establish a diagnosis of a skeletal dysplasia or a rare bone disorder.</li> <li>• Please refer to published coverage policy for details.</li> </ul>
Genetic testing: prenatal and preconception carrier screening	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Ashkenazi Jewish Carrier Panel Testing: Addition of several genetic conditions as eligible for coverage.</li> <li>• Basic carrier screening panels: Addition of this testing as recommended by American College of Obstetricians and Gynecologists (ACOG) guidelines.</li> <li>• Hemoglobinopathy Carrier Screening: Removal of criterion B.iii. stating the member’s reproductive partner is known to have a diagnosis of hemoglobinopathy to align with ACOG guidelines.</li> <li>• Please refer to published coverage policy for details.</li> </ul>
Genetic testing: oncology – cytogenetic testing	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Tumor-Specific ALK Gene Rearrangement (Qualitative FISH and PCR) Tests, Tumor-Specific BCR/ABL1 Gene Rearrangement (Qualitative FISH and PCR) Tests, NTRK Fusion Analysis Panel, Tumor Specific PD-L1 Protein Analysis criteria updated to reflect current NCCN Guidelines: Clarification of Stage 1B or higher disease and addition of covered conditions.</li> <li>• Tumor Specific BCR/ABL Gene Rearrangement (Qualitative FISH and PCR) – Clarification of lymphoma terminology and removal of GIST as a covered condition.</li> <li>• Tumor Specific ERBB2 (HER2) Deletion/Duplication (FISH and CISH) – Addition that member must be considered for trastuzumab or equivalent for gastric cancer. Addition of salivary gland tumors.</li> <li>• NTRK Fusion Analysis Panel – Addition of neuroendocrine carcinoma/large or small cell carcinoma/mixed neuroendocrine-non-neuroendocrine neoplasm.</li> </ul>

Coverage Policies	Comments / Changes
<i>Genetic testing: oncology – cytogenetic testing – cont’d</i>	<ul style="list-style-type: none"> <li>• Tumor Specific PD-L1 Protein Analysis – Clarification of stage IB-III A, IIIB non-small cell lung cancer perioperatively.</li> <li>• Addition of coverage for Tumor Specific FOLR1 Protein Analysis when medical criteria are met.</li> <li>• Tumor Specific RET Gene Rearrangement Tests (FISH): moved from Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies; addition of criteria consistent with NCCN Guidelines.</li> <li>• Please refer to published coverage policy for details.</li> </ul>
Genetic testing: pharmacogenetics	<p>Effective January 1, 2024, policy has been revised</p> <ul style="list-style-type: none"> <li>• Addition of coverage for BCHE, CYP2A5, NAT2, UGT2B17 Variant testing when medical criteria are met.</li> <li>• Addition of covered qualifying drugs for CYP2C9, CYP2C19, CYP2D6, CYP4F2, DPYD, HLA-B*15:02, HLA-B*57:01, TPMT/NUDT15, UGT1A1, VKORC1 Variant Analysis when medical criteria are met.</li> <li>• Criteria for HLA-B*58:01 and HLA-A31:01 were removed.</li> <li>• Please refer to published coverage policy for details.</li> </ul>
Investigational spine procedures	<p>Effective 9/21/2023, total facet arthroplasty (e.g. TOPS system) has been added to this policy. This procedure is considered experimental/investigational and therefore not eligible for coverage. Prior authorization is not applicable.</p>
Genetic testing: oncology – molecular analysis of solid tumors (Commercial and MHCP versions)	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Under broad molecular profiling panel tests: <ul style="list-style-type: none"> <li>○ Addition of one covered indication: the member has newly diagnosed acute lymphoblastic leukemia.</li> <li>○ Addition of repeat molecular profiling panel criteria. Repeat testing is appropriate for those with myelodysplastic syndrome who have relapsed after allogeneic hematopoietic cell transplant, for those with acute lymphoblastic leukemia with evidence of symptomatic relapse after maintenance therapy, or for those with acute myeloid leukemia with relapsed or refractory disease or progression on treatment.</li> </ul> </li> <li>• Addition of a new criteria section into the policy regarding Targeted RNA Fusion panel testing (of 5-50 genes). Indications are listed that would be appropriate for completion of this type of testing (e.g., the member is undergoing workup for lymphoblastic leukemia [pediatric or adult], the member is undergoing workup for histiocytosis or sarcoma, the member has a diagnosis of glioma, etc.).</li> <li>• Broad RNA Fusion panel testing (of 51 or more genes) is considered investigational.</li> <li>• Under colorectal cancer focused molecular profiling panels: <ul style="list-style-type: none"> <li>○ Addition of new indication: The requested panel contains at a minimum the following genes: KRAS, NRAS, and BRAF.</li> </ul> </li> </ul>

Coverage Policies	Comments / Changes
<p><i>Genetic testing: oncology – molecular analysis of solid tumors</i></p> <p><i>(Commercial and MHCP versions) (cont'd)</i></p>	<ul style="list-style-type: none"> <li>• Under Tumor Specific CALR Variant Analysis testing: <ul style="list-style-type: none"> <li>○ Expanding on an indication. The indication: The member is suspected to have a myeloproliferative neoplasm is being expanded to state: The member displays clinical symptoms of a myeloproliferative neoplasm such as chronically elevated red blood cell counts.</li> </ul> </li> <li>• Under Tumor Specific EGFR Variant Analysis: <ul style="list-style-type: none"> <li>○ Clarification of type of carcinomas listed. Rather than advanced or metastatic cancers, a member is to have Stage IB or higher carcinomas to obtain this type of testing.</li> </ul> </li> <li>• Addition of a new criteria section into the policy regarding Tumor Specific ESR1 Variant Analysis testing. Indications are listed that would be appropriate for completion of this type of testing (e.g., the member is a postmenopausal female or adult male with ER-positive and HER2-negative breast cancer and disease progression after one or two prior lines of endocrine therapy, including one line containing a CDK4/6 inhibitor.).</li> <li>• Expanding the criteria set: Tumor Specific KRAS Variant Analysis. The member is to have either suspected or proven metastatic colorectal cancer or the member is to be undergoing workup for metastasis of non-small cell lung cancer.</li> <li>• Under Tumor Specific TP53 Variant Analysis: <ul style="list-style-type: none"> <li>○ Addition of new indication: The member has a diagnosis of acute myeloid leukemia.</li> </ul> </li> <li>• Measurable (minimal) residual disease (MRD) analysis in solid tumor tissue is considered investigational.</li> <li>• Expanding the criteria set: Tumor Mutational Burden. The member is to have either unresectable or metastatic extrahepatic or intrahepatic cholangiocarcinoma.</li> <li>• Please refer to published coverage policy for details.</li> </ul>
<p>Genetic testing: metabolic, endocrine and mitochondrial disorders</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Under Maturity Onset of the Young (MODY) Panels: <ul style="list-style-type: none"> <li>○ Addition of one new indication that needs to be met along with current criteria to approve these types of tests: The member has a family history of diabetes consistent with autosomal dominant inheritance.</li> </ul> </li> <li>• Under the Definitions section in the policy: <ul style="list-style-type: none"> <li>○ Addition of definition of autosomal dominant inheritance.</li> </ul> </li> </ul>

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<p>Genetic testing: hereditary cancer susceptibility (Commercial and MHCP versions)</p>	<p>Effective January 1, 2024, policy has been revised.</p> <ul style="list-style-type: none"> <li>• Under Hereditary GI/Colon Cancer Panel Tests: <ul style="list-style-type: none"> <li>○ Adding one additional gene (TP53) to the list of minimum genes required for this type of testing to be approved once all other criteria are met.</li> </ul> </li> <li>• Under Hereditary Prostate Cancer Susceptibility Panels: <ul style="list-style-type: none"> <li>○ Expanding on acceptable personal and/or family history indications.</li> </ul> </li> <li>• Under FLCN Sequencing and/or Deletion/Duplication Analysis: <ul style="list-style-type: none"> <li>○ Removing indication requiring a member meet two or more of the listed indications. Now, a member need meet any/one of the listed indications.</li> </ul> </li> <li>• APC and/or MUTYH Sequencing and/or Deletion/Duplication Analysis: <ul style="list-style-type: none"> <li>○ Combined what were separate APC and MUTYH criteria sets into one set.</li> <li>○ Adding approvable indications of desmoid tumor, hepatoblastoma and cribriform-morular variant of papillary thyroid cancer.</li> </ul> </li> <li>• Under CDH1 Sequencing and/or Deletion/Duplication Analysis: <ul style="list-style-type: none"> <li>○ Addition of one additional approvable indication: The member has two cases of lobular breast cancer in family members before 50 years of age.</li> <li>○ Removal of indication: The member has a personal history of cancer and a CDH1 pathogenic or likely pathogenic variant was detected by tumor profiling and germline analysis has not yet been performed.</li> </ul> </li> <li>• Under TP53 Sequencing and/or Deletion/Duplication Analysis: <ul style="list-style-type: none"> <li>○ Changing indications regarding number of relatives diagnosed with certain conditions to require an additional first- or second-degree relative diagnosed with cancer and/or sarcoma.</li> <li>○ Addition of one covered indication when a member has a diagnosis of soft tissue sarcoma, osteosarcoma, CNS tumor, or breast cancer diagnosed before 46 years of age. Having a first- or second-degree relative diagnosed with multiple primaries at any age can allow for approval of these types of tests.</li> </ul> </li> <li>• Under MEN1 Sequencing and/or Deletion/Duplication Analysis: <ul style="list-style-type: none"> <li>○ Removal of one indication: The member has a diagnosis of cancer with a pathogenic or likely pathogenic MEN1 variant identified in tumor/somatic genetic testing that may have implications if present in the germline.</li> <li>○ Revision of the remaining criteria: The member is to have a personal history of one of the following diagnoses: duodenal/pancreatic neuroendocrine tumor, primary hyperparathyroidism, pituitary adenoma, or foregut carcinoid and have a family history of at least one of the listed diagnoses (listed above this statement).</li> </ul> </li> <li>• Under RB1 Sequencing and/or Deletion/Duplication Analysis: <ul style="list-style-type: none"> <li>○ Removing "...and has not previously undergone RB1 sequencing and/or deletion/duplication analysis" from the indication stating: The member was to have a family history of retinoblastoma in one or both eyes and has not previously undergone RB1 sequencing and/or deletion/duplication analysis.</li> </ul> </li> <li>• Please refer to published coverage policy for details.</li> </ul>

Coverage Policies	Comments / Changes
Genetic testing: cardiac disorders	<p>Effective 1/1/24, coverage criteria for genetic testing for cardiac disorder will include the following revisions:</p> <ul style="list-style-type: none"> <li>• Criteria for genetic testing for Long QT syndrome will be updated as follows: <ul style="list-style-type: none"> <li>○ Long QT syndrome testing for symptomatic members will be revised to require documentation supporting that a cardiologist has established a strong clinical suspicion for LQTS based on examination of the patient’s clinical history, family history, and expressed electrographic phenotype, or the member has a Schwartz score greater than or equal to 3.0, and Non-genetic causes of a prolonged QTc interval have been ruled out, such as QT-prolonging drugs, hypokalemia, structural heart disease, or certain neurologic conditions including subarachnoid bleed.</li> </ul> </li> <li>• Criteria for genetic testing for Brugada syndrome will be updated as follows. <ul style="list-style-type: none"> <li>○ Clinical information documenting that conditions causing a Brugada syndrome phenocopy (e.g., myocardial ischemia, electrolyte disturbances and drug intoxications) have been ruled out will be required for criteria to be met.</li> <li>○ Additional criteria are revised as follows: <ul style="list-style-type: none"> <li>▪ Member will need to meet any of the following: <ul style="list-style-type: none"> <li>❖ Recurrent syncope documented ventricular fibrillation</li> <li>❖ Self-terminating polymorphic ventricular tachycardia</li> <li>❖ A family history of sudden cardiac death</li> <li>❖ Ventricular fibrillation</li> </ul> </li> <li>○ Genetic testing for Brugada syndrome (BrS) via genes other than SCN5A, including multigene panel analysis, will be considered investigational.</li> </ul> </li> </ul> </li> </ul>
Cosmetic Surgery/treatments – Minnesota Health Care Programs	<p>Effective 9/21/23, a new version of the Cosmetic surgery/treatments specific to Minnesota Health Care Programs (MHCP) members has been posted.</p> <ul style="list-style-type: none"> <li>• It aligns with the MN Department of Human Services guideline that the use of Sculptra™ dermal filler for the treatment of facial lipodystrophy syndrome (LDS) caused by antiretroviral therapy for HIV infection, is now a covered service for MHCP members, effective 8/1/23.</li> <li>• Prior authorization is not required.</li> <li>• See updated policy online.</li> </ul>
Gender-affirming surgery – Minnesota Health Care Programs	<p>Effective 9/8/2023 the policy was revised to reflect updated guidance from DHS.</p> <ul style="list-style-type: none"> <li>• Policy title was changed to Gender-affirming surgery.</li> <li>• See updated policy online.</li> </ul>
Proton beam radiation therapy	<p>Effective 10/1/2023 the policy was revised, and the following conditions were added to the Indications covered section:</p> <ul style="list-style-type: none"> <li>• Primary cancers of the esophagus</li> <li>• Primary benign or malignant bone tumors</li> <li>• Benign or malignant tumors or lymphomas in members aged 21 years and younger</li> </ul>

Coverage Policies	Comments / Changes
Biofeedback	<p>Effective January 1, 2024, this policy has been revised.</p> <ul style="list-style-type: none"> <li>The following condition was added to the Indications that are not covered section: <ul style="list-style-type: none"> <li>PTSD (Post Traumatic Stress Disorder)</li> </ul> </li> </ul>
Hearing Aids	<p>Effective immediately, this policy has been renamed to Bone anchored hearing aids (BAHA).</p> <ul style="list-style-type: none"> <li>This policy is now specific to BAHA.</li> <li>General benefit information related to hearing aids can be found in the member's plan documents.</li> </ul>
Hearing Aids – Minnesota Health Care Programs	<p>Effective immediately, this policy has been renamed to Bone-Anchored Hearing Aids (BAHA).</p> <ul style="list-style-type: none"> <li>This policy is now specific to BAHA.</li> <li>General benefit information related to hearing aids can be found in the DHS Provider Manual, Hearing Aid Services section.</li> </ul>
Complementary and alternative medicine	<p>Effective immediately, policy language was adjusted to reflect coverage of chelation therapy for iron overload conditions (rather than just thalassemia) as this was the initial intent and is supported by existing claims edits.</p> <ul style="list-style-type: none"> <li>Prior authorization is not required.</li> </ul>
Synagis (palivizumab) injections for respiratory syncytial virus (RSV) prophylaxis – Minnesota Health Care Programs	<p>Effective immediately, policy revised. The following language has been added to reflect DHS criteria:</p> <ul style="list-style-type: none"> <li>During the 2023-2024 RSV season, prior authorization request may be approved if the patient meets applicable clinical criteria <b>and</b> one of the following: <ul style="list-style-type: none"> <li>Patient has a contraindication to the RSV immunization (nirsevimab-alip, Beyfortus [Sanofi]) OR</li> <li>Patient is unable to receive the RSV immunization (nirsevimab-alip, Beyfortus [Sanofi])</li> </ul> </li> <li>Prior authorization continues to be required for palivizumab.</li> </ul>

Contact the Medical Policy Intake line at **952-883-5724** for specific patient inquiries.

## Drug Formulary updates

### COMMERCIAL DRUG FORMULARY

Updates include:

- Diabetes GLP-1 medications will update to formulary with prior authorization and a quantity limit starting January 1. This update applies to dulaglutide (Trulicity), exenatide (Bydureon and Byetta), liraglutide (Victoza), semaglutide (Ozempic and Rybelsus) and tirzepatide (Mounjaro).
  - PA: Reserved for members with type 2 diabetes.
  - Approvals are automated for patients with a medical diagnosis claim for diabetes. Other members with type 2 diabetes will require a prior authorization.
  - Tirzepatide (Mounjaro) is being added to the formulary (F-PA-QL) at parity with other diabetes GLP-1 medications.

- Premarin and several Brand hormone replacement products are being removed from the formulary.
  - Premarin oral, Prempro and Premphase, Premarin vaginal cream and Estrin vaginal ring are being removed. Alternatives include estradiol oral, medroxyprogesterone, estradiol vaginal cream and estradiol vaginal tablet (Vagifem, Yuvafem).
- Fluticasone/ salmeterol (Advair Diskus) is being replaced with the equivalent generic.
- Dextroamphetamine/ amphetamine XR (Adderall XR) is being replaced with the equivalent generic.

Updated HSA Preventive Drug Lists are available at [healthpartners.com/hp/pharmacy/druglist](https://healthpartners.com/hp/pharmacy/druglist).

The HSA (Health Spending Account) Preventive Drug Program is meant to promote the use of common medications that enable members to manage chronic conditions such as diabetes, hypertension and high cholesterol. The HSA Preventive Drug Program is used with high-deductible plans to provide these medications for a regular co-pay (without first having to meet a deductible). A second HSA drug list has been created, providing a lower-cost HSA drug list.

- The [Basic HSA Drug List](#) will provide lower-cost options within these categories and will not include medications for asthma and COPD.
- The [Enhanced HSA Drug List](#) will continue to provide broad coverage.

Please see the formulary for details, at [healthpartners.com/formularies](https://healthpartners.com/formularies). Updates will be posted by January 1, 2024.

### WEIGHT LOSS MEDICATIONS

Many insurance plans are excluding weight loss medications starting January 1, 2024, and many members will no longer have coverage. All weight loss medications are affected, including Wegovy, Saxenda, phentermine, Contrave and Qsymia.

Providers are asked to work with patients to determine options and recommendations. Patients can pay out-of-pocket if their plan excludes coverage for these medications. The manufacturers of these medications may offer programs to pay a portion of the costs. HealthPartners offers an array of non-pharmaceutical support for weight management.

Non-pharmaceutical support programs available to Commercial plan members for weight management include:

- Telephonic health coaching that is available to any member with a BMI greater than 30. Health coaches are nationally certified with an average tenure of 12 years at HealthPartners; their experience leads to measurable outcomes including reduced BMI, improved physical activity and improved nutrition.
- All fully insured members meeting qualification criteria have access to Omada's Prevent program. Omada is a virtual care program that helps member achieve health goals through sustainable lifestyle change.
- All members can access digital activities and challenges for weight management, healthy eating and movement through Living Well.

### MINNESOTA HEALTHCARE PROGRAMS (MHCP) DRUG FORMULARY

Updates are available in our online drug formulary.

### MEDICARE DRUG FORMULARY

Updates are available in our online drug formulary.

## Pharmacy Medical Policies

### COMMERCIAL UPDATES

Coverage Policies	Comments / Changes
Oncology – ado-trastuzumab emtansine (Kadcyla®), fam-trastuzumab deruxtecan-nxki (Enhertu®), pertuzumab (Perjeta)	Requiring PA for all oncology uses, to ensure use aligns with FDA indications and NCCN guidelines (currently some diagnoses do not require PA).
Oncology – bevacizumab (Avastin®, Mvasi™, Zirabev®, Alymsys®, Vegzelma®)	Requiring PA for all oncology uses, to ensure use aligns with FDA indications and NCCN guidelines (currently some diagnoses do not require PA).
Oncology – trastuzumab (Herceptin®, Herzuma®, Kanjinti™, Ogivri™, Ontruzant®, Trazimera™), trastuzumab and hyaluronidase-oysk (Herceptin Hylecta™)	Requiring PA for all oncology uses, to ensure use aligns with FDA indications and NCCN guidelines (currently some diagnoses do not require PA).
Oncology – rituximab (Rituxan®, Ruxience™, Truxima®, Rituxan Hycela®, Riabni™)	Requiring PA for all oncology uses, to ensure use aligns with FDA indications and NCCN guidelines (currently some diagnoses do not require PA).
Oncology drug coverage	Adding PA to doxorubicin liposome, panitumumab, cetuximab.

Pharmacy medical policies are available at: [healthpartners.com/public/coverage-criteria/](https://healthpartners.com/public/coverage-criteria/). Updates will be posted by January 1, 2024.

### MEDICAL INJECTABLE SITE OF CARE (MISOC) PROGRAM

Drugs being added to Medical Injectable Site of Care Program

Common Drug Name	Condition	CPT
Lamzede	Enzyme Deficiency	Unclassified
Elfabrio	Enzyme Deficiency	Unclassified
Darzalex Faspro	Immunotherapy	J9144
Darzalex	Immunotherapy	J9145
Zynyz	Immunotherapy	Unclassified

These drugs must be given at a clinic, home infusion, a gold-carded hospital or dispensed through a specialty pharmacy if provided at a high-cost hospital.

### SELF-ADMINISTERED DRUGS POLICY UPDATES

This policy identifies self-administered drugs that are only available for coverage under a member's pharmacy benefit, subject to the member's coverage document. The following additions are effective January 1, 2024.

Brand Name	Generic Name
CORTROPHIN	corticotropin
MOUNJARO	tirzepatide

## POLICIES AND CONTACT INFORMATION

Quarterly Formulary Updates and additional information such as Prior Authorization and Exception Forms, Specialty Pharmacy information, and Pharmacy and Therapeutics Committee policies are available at [healthpartners.com/provider/admin\\_tools/pharmacy\\_policies](https://healthpartners.com/provider/admin_tools/pharmacy_policies), including the [Drug Formularies](#).

Pharmacy Customer Service is available to providers (physicians and pharmacies) 24 hours per day and 365 days per year.

- Fax: **952-853-8700** or **1-888-883-5434** Telephone: **952-883-5813** or **1-800-492-7259**
- HealthPartners Pharmacy Services, 8170 33rd Avenue South, PO Box 1309, Mpls, MN 55440

HealthPartners Customer Service is available from 8 AM - 6 PM Central Time, Monday through Friday, and 8 AM – 4 PM Saturday. After hours calls are answered by our Pharmacy Benefit Manager.

For additional information, please contact [healthpartnersclinicalpharmacy@healthpartners.com](mailto:healthpartnersclinicalpharmacy@healthpartners.com).

## Disclosure of Ownership and Control Interest Form

HealthPartners has automated the process for providers to submit their Disclosure of Ownership information. The primary contact on file for your organization will receive an e-mail with a link to the form. There will be information that will need to be verified, updated and attested to, along with a place for a signature and date. The Minnesota Department of Human Services (DHS) and the Centers for Medicare and Medicaid Services (CMS) requires health plans, including HealthPartners, to collect information from their contracted providers regarding ownership and control interests, management information, significant business transactions, and the identity of any individuals or entities excluded from participating in government funded health care programs.

If your primary contact has not received the link and submitted a 2023 Disclosure of Ownership and Control Interest Form yet, please click on the link below to print a copy of the form for completion. The form is required to be completed on an annual basis or when changes to ownership occur.

- [Disclosure of Ownership Form – HealthPartners](#)

If you are a participating provider with other Minnesota payers, any payer will accept this form, so it can be completed once and submitted to any payer with whom you are contracted.

Please submit the form to HealthPartners in one of the following ways:

- Email: [disclosureofownership@healthpartners.com](mailto:disclosureofownership@healthpartners.com)
- Fax: **952-853-8708**

## Physician Incentive Plans (PIP) disclosure

The Centers for Medicare and Medicaid Services (CMS) requires health plans to request information from their contracted providers regarding the existence of physician incentive plans. The information should also include any physician incentive plans that exist between your organization and downstream subcontractors. Physician Incentive Plan disclosure is required even if there are no incentive arrangements or the arrangements have a low level of risk either through referrals or low utilization. If your information has changed since your organization last submitted this form, please submit the fax back form that's attached to this edition of Fast Facts to HealthPartners and a Summary Data Form will be sent to you for completion.

Thank you in advance for your assistance in keeping physician incentive plan information up to date. For more information from CMS on Physician Incentive Plans, please click [CMS Relationships with Providers](#) and review Section 80.

If you have questions or need more information, please contact your Service Specialist.