

Genetic Testing for Hereditary Ataxias



INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

Genetic Testing
Genetic Testing for Diagnosis of Inherited Conditions
Skyclarys (omaveloxolone)

Related Documents

Please refer to [CMS website](#) for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare	Applicable States/Territories
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			Administrative Contractors (MACs)	
LCD	MolDX: Molecular Diagnostic Tests (MDT)	L36807	J5, J8 - Wisconsin Physicians Service Insurance Corporation	IA, IM, KS, MI, MO, NE
LCD LCA	Molecular Pathology Procedures Billing and Coding: MolDX: Molecular Pathology Procedures	L35000 A56199	J6, JK - National Government Services, Inc.	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
LCD	MolDX: Molecular Diagnostic Tests (MDT)	L36021	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD	MolDX: Molecular Diagnostic Tests (MDT)	L35160	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD	MolDX: Molecular Diagnostic Tests (MDT)	L36256	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD	Biomarkers Overview	L35062	JH, JL - Novitas Solutions, Inc.	AR, CO, DE, LA, MD, MS, NJ, NM, OK, PA, TX, D.C.
LCD	MolDX: Molecular Diagnostic Tests (MDT)	L35025	JJ, JM - Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
LCD LCA	Molecular Pathology Procedures Billing and Coding: MolDX: Molecular Pathology and Genetic Testing	L34519 A58918	JN - First Coast Service Options, Inc.	FL, PR, U.S. VI

Description

The hereditary ataxias are a group of genetic disorders characterized by motor incoordination that results from dysfunction of the cerebellum and/or spinal cord that is associated with dysarthria (abnormal speech), poor eye-hand coordination and an unsteady gait. These disorders are categorized by mode of inheritance and causative gene or chromosomal locus. Hereditary ataxias can be inherited in an autosomal dominant, autosomal recessive or X-linked manner.

Friedreich ataxia (FRDA) is a germline, autosomal-recessive, progressive, neurodegenerative disorder and is the most common hereditary ataxia. FRDA is caused by mutations in the *FXN* gene on chromosome 9 which

produces a protein called frataxin. It is characterized by progressive ataxia with onset starting between 5 and 15 years of age. Symptoms typically associated with the disorder include absent lower-limb reflexes, bladder dysfunction, dysarthria, muscle weakness, spasticity particularly in the lower limbs and scoliosis.²⁵ Diabetes mellitus and heart-related conditions (eg, atrial fibrillation, cardiomegaly, cardiomyopathy, heart murmurs, tachycardia) are also associated with FRDA.

Spinocerebellar ataxia (SCA) is a germline, autosomal-dominant, progressive, neurodegenerative disease. It is characterized by dysfunction of the cerebellum (the part of the brain that controls walking and balance) and is manifested by progressive uncoordinated movements (ataxia). There are over 40 different types of SCA conditions. They typically present in middle age with progressive ataxia, neuronal dysfunction and eventual neuronal loss during the ensuing 10 to 20 years.

Cerebellar ataxia with neuropathy and vestibular areflexia syndrome (CANVAS) is a germline, autosomal recessive, adult-onset, slowly progressive neurologic disorder characterized by imbalance due to cerebellar gait and limb ataxia, impaired vestibular function bilaterally and non-length-dependent sensory neuropathy.⁴⁸

Diagnostic genetic testing may be used for an individual with signs and symptoms of CANVAS, FRDA and SCA. Genetic testing has also been proposed for an at-risk individual with a family history of FRDA and SCA.

Multigene panels have been proposed to evaluate genes associated with diseases or syndromes. Panels often include medically actionable genes but may also include those with unclear medical management (eg, ataxia repeat expansion and sequence analysis [eg, Genomic Unity (0216U)] and comprehensive ataxia repeat expansion and sequence analysis [eg, Genomic Unity (0217U)]

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Genetic tests must demonstrate clinical utility, analytical and clinical validity and fulfill the CMS “reasonable and necessary” criteria. Analytic validity (test accurately identifies the gene variant), clinical validity (test identifies or predicts the clinically defined disorder) and clinical utility (test measurably improves clinical outcomes) of the genetic test is supported by generally accepted standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, specialty society recommendations, and views of physicians practicing in relevant clinical areas. The test must be ordered by a physician who is treating the beneficiary and the results will be used in the management of a beneficiary’s specific medical problem.

For jurisdictions with no Medicare guidance for a particular test, iCare will utilize the [MolDX program](#) and Technical Assessments for molecular assays as the standard to evaluate clinical utility, analytical and clinical validity in conjunction with adhering to Medicare’s reasonable and necessary requirement.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

General Criteria for Genetic Testing for Hereditary Ataxias

Apply general criteria for genetic testing for hereditary ataxias when disease- or gene-specific criteria are not available on this medical coverage policy.

Genetic testing for hereditary ataxias will be considered medically reasonable and necessary if:

- Analytic validity, clinical validity and clinical utility of the panel is supported by the [MolDX program](#); **AND**
- Alternative laboratory or clinical tests to definitively diagnose the disorder/identify the condition are unavailable or results are clearly equivocal; **AND**
- Results of the genetic testing must directly impact treatment or management of the Medicare beneficiary

Criteria for Specific Hereditary Ataxias

GERMLINE (HEREDITARY) TESTING:

Cerebellar Ataxia with Neuropathy and Vestibular Areflexia Syndrome (CANVAS) (RFC1 Gene)

Genetic testing of RFC1 gene (eg, 0378U) will be considered medically reasonable and necessary to aid in the diagnosis of CANVAS when the following requirements are met:

- Individual to be tested exhibits at least 2 of the following signs and symptoms of CANVAS (progressive gait and limb incoordination, imbalance, dysarthria and disturbances of eye movements); **AND**
- Nongenetic causes of ataxia have been excluded (eg, alcoholism, multiple sclerosis, primary or metastatic tumors or paraneoplastic diseases associated with occult carcinoma of the ovary, breast or lung, vascular disease, vitamin deficiencies)

Testing strategy: Targeted analysis for repeat AAGGG expansions²⁸

Friedreich Ataxia (FRDA) (FXN Gene)

Genetic testing of FXN gene (eg, Genomic Unity FXN analysis [0233U]) will be considered medically reasonable to aid in the diagnosis of FRDA and necessary when the following requirements are met:

- Individual to be tested exhibits at least 2 of the following signs and symptoms of FRDA (progressive gait and limb incoordination, imbalance, dysarthria and disturbances of eye movements); **AND**

- Nongenetic causes of ataxia have been excluded (eg, alcoholism, multiple sclerosis, primary or metastatic tumors or paraneoplastic diseases associated with occult carcinoma of the ovary, breast or lung, vascular disease, vitamin deficiencies)

Testing strategy: Testing begins with *FXN* expanded allele analysis (to detect expanded GAA repeat in intron 1 of *FXN*). If only 1 abnormal expanded allele is identified, perform sequence analysis. Perform deletion/duplication analysis if no pathogenic variant is detected on sequence analysis.²⁵

Spinocerebellar Ataxia (SCA) (*ATXN1*, *ATXN2*, *ATXN3*, *CACNA1A*, *ATXN7* and *ATN1* Genes)

A [targeted multigene panel](#) that includes the following genes: *SCA1* (*ATXN1* gene), *SCA2* (*ATXN2* gene), *SCA3* (*ATXN3* gene), *SCA6* (*CACNA1A* gene), *SCA7* (*ATXN7*) and dentatorubral-pallidoluysian atrophy (*DRPLA*) (*ATN1* gene) will be considered medically reasonable and necessary to aid in the diagnosis of SCA when the following requirements are met:

- Individual to be tested exhibits at least 2 of the following signs and symptoms of SCA (eg, progressive gait and limb incoordination, imbalance, dysarthria and disturbances of eye movements); **AND**
- Nongenetic causes of ataxia have been excluded (eg, alcoholism, multiple sclerosis, primary or metastatic tumors or paraneoplastic diseases associated with occult carcinoma of the ovary, breast or lung, vascular disease, vitamin deficiencies)

Testing strategy:^{29 to 44}

1. Testing begins with single gene or targeted multigene trinucleotide repeat testing of *ATN1*, *ATXN1*, *ATXN2*, *ATXN3*, *ATXN7* and *CACNA1A*
2. If results of the above gene(s) analysis are normal and a high index of suspicion remains for SCA based on clinical findings, perform single gene trinucleotide repeat testing of any of the following genes:
 - 11q12
 - *AFG3L2*
 - *ATXN10*
 - *ATXN8*
 - *ATXN8OS*
 - *DAB1*
 - *ELOVL5*
 - *FGF14*
 - *ITPRI*
 - *KCNC3*
 - *PPP2R2B*
 - *PRKCG*
 - *SPTBN2*
 - *TBP*
 - *TTBK2*

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

[US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage](#)

The following tests may not be considered a benefit (statutory exclusion):

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law;⁴⁶ **OR**
- Tests that confirm a diagnosis or known information;⁴⁶ **OR**
- Tests that investigate the same germline genetic content, for the same genetic information, that has already been tested in the same individual;^{9,10} **OR**
- Tests to determine risk for developing a disease or condition;⁴⁶ **OR**
- Tests performed to measure the quality of a process;⁴⁶ **OR**
- Tests without diagnosis specific indications;⁴⁶ **OR**
- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial⁴⁶

These treatments and services fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services/items fall within the Medicare program's statutory exclusion at 1862(a)(12), which prohibits payment.

The following items will not be considered medically reasonable and necessary:

- Multigene ataxia repeat expansion and sequence analysis panels^{9,10}
- *CACNA1A* full gene sequence analysis (eg, 81185, 0231U)^{25,31}

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Ataxia Repeat Expansion and Sequence Analysis

For testing panels, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing would be covered ONLY for the number of genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making.⁹

CACNA1A full gene sequence analysis

Several types of SCAs (SCA1, SCA2, SCA3, SCA6, SCA7, SCA12, SCA17) and DRPLA are associated with expansion of cytosine-adenine-guanine (CAG) repeats in the region that encodes for polyglutamine tracts in the protein products. The age of onset and rate of disability progression vary according to individual differences in the length of the causative CAG trinucleotide repeat. The diagnosis of SCA6 is established in a proband with a heterozygous CAG repeat expansion in *CACNA1A* by molecular genetic testing.^{31,45}

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
81177	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	
81178	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	
81179	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	
81180	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	
81181	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	

81183	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles	
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence	
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant	
81284	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles	
81285	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)	
81286	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence	
81289	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)	
81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	
81344	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles	
81401	MOLECULAR PATHOLOGY PROCEDURE LEVEL 2	
81406	MOLECULAR PATHOLOGY PROCEDURE LEVEL 7	
81407	MOLECULAR PATHOLOGY PROCEDURE LEVEL 8	
81479	Unlisted molecular pathology procedure	
0216U	Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants	
0217U	Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants	

0231U	CACNA1A (calcium voltage-gated channel subunit alpha 1A) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions	
0233U	FXN (frataxin) (eg, Friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (STR) expansions, mobile element insertions, and variants in non-uniquely mappable regions	
0378U	RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat-primed PCR, blood, saliva, or buccal swab	
CPT® Category III Code(s)	Description	Comments
No code(s) identified		
HCPCS Code(s)	Description	Comments
No code(s) identified		

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Change Summary

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