

Corporate Medical Policy

DNA Based Testing for Adolescent Idiopathic Scoliosis

File Name: dna_based_testing_for_adolescent_idiopathic_scoliosis
Origination: 10/2011
Last CAP Review: 2/2012
Next CAP Review: 2/2013
Last Review: 2/2012

Description of Procedure or Service

Adolescent idiopathic scoliosis (AIS) is the most common pediatric spinal deformity affecting 1 to 3% of adolescents. This disease, of unknown etiology, occurs in otherwise healthy children with the onset highly correlated with the adolescent growth spurt. The vertebrae become misaligned such that the spine deviates from the midline laterally and becomes rotated axially. Deviation can occur anteriorly (a lordotic deviation) or posteriorly (a kyphotic deviation). Although AIS affects females and males in a nearly 1:1 ratio, progression to severe deformity occurs more often in females. Because the disease can have rapid onset and produce considerable morbidity, school screenings have been recommended. However, screening remains somewhat controversial, with conflicting guidelines supporting this practice or alternatively suggesting insufficient evidence for this.

The familial nature of this disease was noted as early as 1968. About one-quarter of patients report a positive family history of disease and twin studies have consistently supported shared genetic factors. Genome-wide linkage studies have reported multiple chromosomal regions of interest, often not replicated. DNA testing to predict the risk of progression of AIS is a novel development in the field of genetics.

Regulatory Status

The ScoliScoreTMAIS (adolescent idiopathic scoliosis) prognostic DNA-based test (Axial Biotech, Salt Lake City, UT) has not been approved or cleared by the U.S Food and Drug Administration (FDA), but is being offered as a laboratory-developed test. The laboratory performing this test is accredited by the Centers for Medicare and Medicaid (CMS) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

DNA based testing for adolescent idiopathic scoliosis is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

DNA Based Testing for Adolescent Idiopathic Scoliosis

When DNA Based testing for Adolescent Idiopathic Scoliosis is covered

Not Applicable

When DNA Based Testing for Adolescent Idiopathic Scoliosis is not covered

DNA based testing for adolescent idiopathic scoliosis is considered investigational. BCBSNC does not cover investigational services or procedures.

Policy Guidelines

The ScoliScore™ AIS (adolescent idiopathic scoliosis) prognostic DNA-based test (Axial Biotech, Salt Lake City, UT) is a saliva-based genetic test designed to predict the risk of progression of scoliosis in patients with AIS. The test uses an algorithm incorporating results of testing for 53 single nucleotide polymorphisms (SNPs) along with the patient's presenting spinal curve (Cobb angle) to generate a risk score (ranging from 1 to 200), which can be used qualitatively or quantitatively to predict the likelihood of spinal curve progression. The test is intended for white (Caucasian) patients with a primary diagnosis of AIS between the ages of 9 and 13 years old with a mild scoliotic curve (defined as $<25^\circ$).

The clinical utility of the test remains unknown. There is no direct evidence demonstrating that use of this test results in changes in management that improve outcomes. The value of early identification and intervention(s) for individuals at risk for progression of disease is unclear. As a result, DNA-based testing for AIS is considered investigational until results of further research on both clinical validity and utility have been reported.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: There is no specific CPT code for this test. A series of molecular diagnostic codes such as 83891, 83898, 83903, 83012 would likely be used.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Lonstein JE, Carlson JM. The prediction of curve progression in untreated idiopathic scoliosis during growth. *J Bone Joint Surg Am* 1984; 66(7):1061-71.

Peterson LE, Nachemson AL. Prediction of progression of the curve in girls who have adolescent idiopathic scoliosis of moderate severity. Logistic regression analysis based on data from The Brace Study of the Scoliosis Research Society. *J Bone Joint Surg Am* 1995; 77(6):823-7.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.04.74, 8/11/11

DNA Based Testing for Adolescent Idiopathic Scoliosis

Specialty Matched Consultant Advisory Panel review 2/2012

Policy Implementation/Update Information

10/11/11 New policy developed. DNA based testing for adolescent idiopathic scoliosis is not covered. It is considered investigational. BCBSNC does not cover investigational services or procedures. Medical Director review 8/2011. (mco)

3/20/12 Specialty Matched Consultant Advisory Panel review 2/2012. No changes to policy statement. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.