Protocol

DNA-Based Testing for Adolescent Idiopathic Scoliosis

(20474)

Medical Benefit		**Effective Date**: 04/01/12	**Next Review Date**: 09/14
Preauthorization	No	**Review Dates**: 01/12, 09/12, 09/13	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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 one 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 nine and 13 years with a mild scoliotic curve (defined as < 25°).

Background

Adolescent idiopathic scoliosis (AIS) is the most common pediatric spinal deformity, affecting 1% to 3% of adolescents. (1) This disease, of unknown etiology, occurs in otherwise healthy children with the onset of, and 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.

Diagnosis is established by radiologic observation in adolescents (age 10 years until the age of skeletal maturity) of a lateral spine curvature of 10 degrees or more, as measured using the Cobb angle. (2) The Cobb angle is defined as the angulation measured between the maximally tilted proximal and distal vertebrae of the curve. Curvature is considered mild (less than 25°), moderate (25° to 40°), or severe (more than 40°) in an individual still growing. Once diagnosed, patients must be monitored over several years, usually with serial radiographs for curve progression. If the curve progresses, spinal bracing is the generally accepted first-line treatment. If the curve progresses in spite of bracing, spinal fusion may be recommended.

Curve progression has been linked to a number of factors, including sex, curve magnitude, patient age, and skeletal maturity. Risk tables have been published by Lonstein and Carlson (3) and Peterson and Nachemson (4) to help in triage and treatment decision making about patients with AIS. Tan et al (5) have recently compared a broad array of factors and concluded that using 30 degrees as an endpoint, initial Cobb angle magnitude produces the best prediction of progression outcome.

The familial nature of this disease was noted as early as 1968. (6) About one quarter of patients report a positive family history of disease, and twin studies have consistently supported shared genetic factors. (1) Genome-wide linkage studies have reported multiple chromosomal regions of interest, often not replicated. Ogilvie has recently suggested AIS is a complex polygenic trait. (7) He and colleagues at Axial Diagnostics have published a study evaluating an algorithm using 53 SNP markers identified from unpublished genome-wide association studies (GWAS) to identify patients unlikely to exhibit severe progression in curvature versus those at considerable risk for severe progression. The clinical validity of this assay has recently been reported in a retrospective case control cohort study using this algorithm. (2)

Regulatory Status

The ScoliScore™ AIS (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).

FDA has indicated an interest in changing its policy for use of enforcement discretion in the oversight of laboratory-developed tests, but the status of this proposed change in policy and the impact of any particular laboratory-developed test are currently unknown.

Corporate Medical Guideline

DNA-based prognostic testing for adolescent idiopathic scoliosis is considered **investigational**.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Weinstein SL, Dolan LA, Cheng JC et al. Adolescent idiopathic scoliosis. Lancet 2008; 371(9623):1527-37.
2. Ward K, Ogilvie JW, Singleton MV et al. Validation of DNA-based prognostic testing to predict spinal curve progression in adolescent idiopathic scoliosis. Spine (Phila Pa 1976) 2010; 35(25):E1455-64.
3. 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.
4. 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.

5. Tan KJ, Moe MM, Vaithinathan R et al. Curve progression in idiopathic scoliosis: follow-up study to skeletal maturity. Spine (Phila Pa 1976) 2009; 34(7):697-700.
6. Wynne-Davies R. Familial (idiopathic) scoliosis. A family survey. J. Bone Joint Surg. Br. 1968; 50(1):24-30.
7. Ogilvie J. Adolescent idiopathic scoliosis and genetic testing. Curr. Opin. Pediatr. 2010; 22(1):67-70.
8. Sharma S, Gao X, Londono D et al. Genome-wide association studies of adolescent idiopathic scoliosis suggest candidate susceptibility genes. Hum. Mol. Genet. 2011; 20(7):1456-66.
9. Ogura Y, Takahashi Y, Kou I et al. A Replication Study for Association of 53 Single Nucleotide Polymorphisms in a Scoliosis Prognostic Test With Progression of Adolescent Idiopathic Scoliosis in Japanese. Spine (Phila Pa 1976) 2013.
10. Roye BD, Wright ML, Williams BA et al. Does ScoliScore provide more information than traditional clinical estimates of curve progression? Spine (Phila Pa 1976) 2012 [Epub ahead of print].