

Policy Name:	Genetic Testing: ScolioScore™ Adolescent Idiopathic Scoliosis (AIS) Prognostic Test
Current Policy Effective Date:	8/20/2018

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

ScolioScore™ Adolescent Idiopathic Scoliosis (AIS) Prognostic Test for the prediction of spinal curve progression is investigative and therefore NOT COVERED.

Description

Adolescent idiopathic scoliosis (AIS) is a spine deformity characterized by lateral and rotational curvature of the spine. Its cause is unknown, although progress has been made in the genetic study of the disorder. Diagnosis of the disorder is usually straightforward, as mild curvatures can be detected visibly or by a forward bending test, scoliometer, or x-ray. Progression of the curve is unpredictable, and a subset of children with AIS may exhibit rapid progression.

Seven to 10% of approximately 100,000 patients diagnosed with mild scoliosis each year progress to requiring bracing, and 1% to 4% will require surgical intervention. Therefore, a prognostic test that would identify those with the highest risk of progression is desirable. Such a test could reduce the amount of radiologic and observational monitoring required for low-risk patients. ScolioScore™ AIS Prognostic Test is a multi-gene test that purports to provide a qualitative and quantitative assessment of the likelihood of spinal curve progression for patients who have been diagnosed with AIS.

FDA Approval

Genetic tests are regulated under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. Pre-market approval from the FDA is not required as long as the assay is performed in a laboratory facility that observes CLIA regulations and the test is not marketed for general distribution. The ScolioScore AIS Prognostic Test was developed by Axial Biotech, Inc. in 2009. In 2012 Transgenomic, Inc. acquired the rights to the ScolioScore test.

Medica Coverage Policy



Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

- 81479 – unlisted molecular pathology procedure
- 84999 – unlisted chemistry procedure
- 88299 – unlisted cytogenetic study

Original Effective Date: 9/1/2012

Re-Review Date(s): 6/17/2015
6/12/2018

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