



Physician Frequently Asked Questions for SHARP™ Reimbursement Program for ScolioScore™



For more info on the
SHARP™ Reimbursement
Program call: **877-SHARP10**
(877-742-7710)

Q: What is the SHARP™ Reimbursement Program for ScolioScore™?

A: The SHARP Reimbursement Program has been developed to provide an extensive selection of reimbursement services for the families of patients receiving the ScolioScore™ AIS Prognostic Test. These services include submitting all claims to insurers, managing the appeals process if necessary, and providing financial assistance that may lessen or eliminate financial responsibility for self-pay patients who are not covered by their insurance.

Q: Who is eligible for the SHARP Program?

A: Any patient for whom physicians believe ScolioScore™ is medically necessary is eligible for SHARP services. Please call **877-SHARP10 (877-742-7710)** and a reimbursement counselor will answer any questions that you or your patient might have.

Q: Will physician's clinics need to bill patient's insurance?

A: No, Axial Biotech will assume all responsibility for billing the ScolioScore™ test. Furthermore, clinics will not be charged for the ScolioScore™ specimen collection kits.

Q: What is the price of the ScolioScore™ test?

A: ScolioScore™ is priced at \$2950. This price is based on the CMS Clinical Lab Fee Schedule and is commensurate with other new molecular diagnostic technologies such as Oncotype DX, BRCA, Allo-Map® and PathFinderTG®.

Q: Are there CPT codes for the ScolioScore™ Test?

A: Yes, Axial Biotech uses existing CPT codes that are well established for molecular diagnostic testing. This is a significant advantage over other new tests that rely on unlisted codes that can greatly complicate the billing process and reduce the likelihood that the test will be covered.

Q: Will I be able to bill for any portion of my services when ordering Scoliscore™?

A: No, because Axial Biotech bills the Scoliscore™ test directly to insurance payers, there are no codes that are billable by the physician.

Q: What will my clinic need to do to help my patients receive coverage for the Scoliscore™ Test?

A: As with any new technology, there may be times when insurance payers will ask physicians for additional information to gain third party reimbursement on behalf of their patients. This information may include:

- Requests for Letters of Medical Necessity that demonstrate why the test was ordered for that patient and how the information will be used
- Copy of patient records, medical notes, radiographs
- Letters to payers to support positive coverage policies

Q: Do I need a patient consent form signed before ordering Scoliscore™?

A: No, the only signatures that are needed when submitting a Scoliscore™ sample are the physician's signature and the signature of the responsible insured party (parent or guardian), authorizing Axial Biotech to bill the insurer on their behalf.

Q: Should my patients be concerned that insurers could use their genetic information inappropriately?

A: No, with the passing of GINA (Genetic Information Non-Disclosure Act) in September 2008, no insurer or employer is allowed to use any genetic information to discriminate in any way. In addition, Axial Biotech will only be looking at the genetic markers that determine the likelihood of curve progression for patients diagnosed with scoliosis.

Q: Is Scoliscore™ approved by the FDA?

A: The Scoliscore™ test is lawfully marketed as a Laboratory-Developed Test (LDT) regulated under CMS by the Clinical Laboratory Improvement Amendments (CLIA). No pre-market clearance under the Federal Food, Drug and Cosmetic Act [FFDCA] § 510(k) or Pre-Market Approval (PMA) by the Food and Drug Administration (FDA) is required at this time.

Questions? Call a SHARP Representative at 877-SHARP10 (877-742-7710)