PGxHealth Reimbursement Services

Introduction

- The reimbursement environment for the *FAMILION* tests for inherited cardiac syndromes has improved significantly during the past three years.
- PGxHealth is devoting increasing resources to assist patients with reimbursement services.

PGxHealth Reimbursement Services

- PGxHealth will assist each patient by working with the insurance provider to pre-authorize services and determine benefit information upon request.
- PGxHealth will contact the patient with this information prior to the initiation of testing.
- PGxHealth will be quoted an estimate of coverage from the insurance carrier and cannot guarantee reimbursement.
- Following the completion of testing, PGxHealth will file the insurance claim with the provider.

For additional information, please contact PGxHealth's Customer Service team at 877-2-PGxHealth (877-274-9432) or visit www.pgxhealth.com

Select Commercial Payers With Supportive Coverage Policies

- Aetna
- Cigna
- Harvard Pilgrim
- Health Net, Inc.
- HIP Plan of NY
- Humana
- Select Health
- Tufts Health

Select Government Payers With Supportive Coverage Policies

- TriCare

PGxHealth—An Approved Medicaid Provider

- PGxHealth has applied to be an approved Medicaid provider in all 50 states.
- The following states have approved PGxHealth's application to be a Medicaid provider (as of mid-March 2008):
  - New York
  - Illinois
  - Pennsylvania
  - Arizona
  - Washington
  - Indiana
  - Minnesota
  - Wisconsin
  - Colorado
  - Oregon
  - Oklahoma
  - Iowa
  - Kansas
  - Utah
  - West Virginia
  - Idaho
  - Maine
  - Montana
  - Vermont

The *FAMILION*® Tests—Select Coverage Policies

Blue Cross Blue Shield Technical Evaluation Center (TEC)

http://www.bcbs.com/betterknowledge/tec/vols/22/22_09.html
Full report available at http://www.bcbs.com/betterknowledge/tec/vols/22/22_09.pdf

The TEC Committee concluded that:

- Genetic testing for long QT syndrome (LQTS) meets the Blue Cross Blue Shield TEC criteria for establishing the diagnosis of LQTS in the following patient populations:

  Individuals who do not meet the clinical criteria for LQTS but who have: A close relative (first-, second-, or third-degree relative) with a known LQTS mutation; or

  A close relative diagnosed with LQTS by clinical means whose genetic status is unavailable; or

  Signs and/or symptoms indicating a moderate to high pre-test probability of LQTS.

  An individual who meets the clinical criteria for LQTS and has a close relative at risk for LQTS is an indication for genetic testing. In this circumstance, testing of the individual with LQTS is intended to inform genetic testing options for at-risk relatives.

- Genetic testing for LQTS does not meet the TEC criteria for determining prognosis and/or directing therapy in patients with known LQTS who do not have close relative(s) with indications for genetic testing.

  Determining the pre-test probability of LQTS is not standardized. An example of a patient with a moderate to high pre-test probability of LQTS is a patient with a Schwartz score of 2-3.

Aetna

http://www.aetna.com/cpb/medical/data/100_199/0140.html

Aetna considers genetic testing for LQTS medically necessary for EITHER of the following:

- Persons with a prolonged QT interval on resting electrocardiogram (a corrected QT interval (QTc) of ≥470 msec in males and ≥480 msec in females) without an identifiable external cause for QTc prolongation (such as heart failure, bradycardia, electrolyte imbalances, certain medications and other medical conditions); or

- Members with first-degree relatives (siblings, parents, offspring) with LQTS or with a defined LQTS mutation.

Aetna considers genetic testing for LQTS experimental and investigational for all other indications.

Cigna

http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0193_coveragepositioncriteria_genetic_testing_for_long_qt_syndrome.pdf

- For confirmatory testing when the patient has been confirmed to have a prolonged QT interval on electrocardiogram or Holter monitor, and an acquired cause has been ruled out.

- For predictive testing in EITHER of the following situations:

  When the individual is the reproductive partner of a person with a positive genetic test for LQTS and the couple has the capacity and intention to reproduce.

  When there is evidence of EITHER of the following situations in a first-degree relative*:
  - There is a history of prolonged QT interval on electrocardiogram or Holter monitor, sudden death, or near sudden death and a genetic syndrome is suspected.

  - There is a positive genetic test for LQTS.

All individuals undergoing genetic testing for any reason should have both pre- and post-test genetic counseling with a physician or a licensed or certified genetic counselor.

**A first-degree relative is defined as a blood relative with whom an individual shares approximately 50% of his/her genes. First-degree relatives include the individual's parents, full siblings and children.*

Humana

http://apps.humana.com/TAD/TAD_New/returnContent.asp?mime=application/pdf&id=5298&issue=608

Humana members would be eligible under the plan for genetic testing for LQTS for ANY of the following indications:

- Member has been confirmed to have a prolonged QT interval on electrocardiogram or Holter monitor, and an acquired cause has been ruled out (such as heart failure, bradycardia, electrolyte imbalances or certain medications); or

- Members with first-degree* relatives with LQTS or with a defined LQTS mutation.

**First-degree relatives include member's parents, full siblings and children.*

HIP Plan of New York

https://www.hipusa.com/providers/ny/guidelines/pdf/lab/MG_Long_QT_Testing.pdf

Members are eligible for coverage of LQTS genetic testing when either of the following criteria is documented as met:

- Presence of a prolonged QT interval on resting electrocardiogram or Holter monitor (realtime cardiac monitoring acceptable for Medicare or Medicaid members) in the absence of an identifiable etiology (heart failure, bradycardia, electrolyte imbalances, certain medications, etc.).
- Members with first-degree relatives (children, siblings, parents) who have LQTS or a known LQTS mutation.

Tufts Health Plan

http://www.tuftshealthplan.com/providers/pdf/mng/Genetic_Testing_Long_QT.pdf

Tufts Health Plan may authorize coverage of genetic testing for LQTS if either of the following criteria is met:

- The member has a prolonged QT interval on resting electrocardiogram or Holter monitor, and evaluation by a cardiologist has not identified any causative factors.
- The member has a first-degree relative (parents, siblings and offspring only) with one of the following:

  Diagnosis of LQTS

  Known LQTS mutation

Testing must be performed at a contracting laboratory facility when available.

Health Net, Inc.

https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/genetic_testing_long_qt_syndrome_apr_07.pdf

Health Net, Inc. considers genetic testing for LQTS medically appropriate when any of the following criteria is met:

- The patient has been confirmed to have prolonged QT interval documented on electrocardiogram and/or Holter monitor, and acquired causes have been ruled out (such as drugs); or
- There is a positive family history of sudden death in an individual of <30 years of age, and a genetic syndrome is suspected; or
- There is a positive genetic test in a first-degree relative (parents, full siblings and/or children).

FAMILION®
Genetic Tests for Inherited Cardiac Syndromes
1-877-2-PGX-Health (1-877-274-9432)

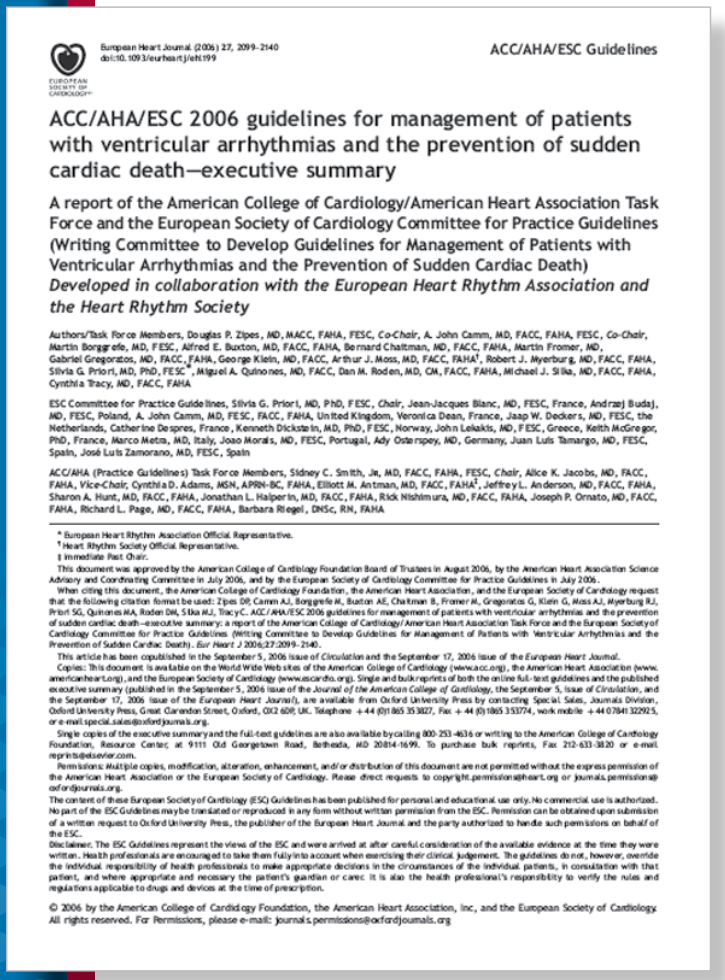
ACC/AHA/ESC Guidelines (2006) Recommend Genetic Testing to Identify ALL Mutation Carriers in an LQTS Family

The ACC/AHA/ESC guidelines for management of patients with ventricular arrhythmias and prevention of sudden cardiac death recommend genetic testing for numerous congenital cardiac diseases including those that can identified by the *FAMILION* tests.

http://circ.ahajournals.org/cgi/reprint/114/10/1088

Long QT Syndrome:

"Genetic analysis is very important for identifying all mutation carriers within an LQTS family: Once identified, silent carriers of LQTS genetic defects may be treated with beta-blockers for prophylaxis of life-threatening arrhythmias. Furthermore, silent mutation carriers should receive genetic counseling to learn about the risk of transmitting LQTS to offspring."



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ACC/AHA/ESC Guidelines

ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death—executive summary

A report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death)
Developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society

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Single copies of the executive summary and the full-text guidelines are also available by calling 800-253-4636 or writing to the American College of Cardiology Foundation, Resource Center, at 9111 Old Georgetown Road, Bethesda, MD 20814-1699. To purchase bulk reprints, Fax 212-633-3820 or e-mail reprints@elsevier.com.

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"In patients affected by LQTS, genetic analysis is useful for risk stratification and for making therapeutic decisions. Although genetic analysis is not yet widely available, it is advisable to try to make it accessible to LQTS patients."

Catecholaminergic Polymorphic Ventricular Tachycardia:

"Genetic analysis may help identify silent carriers of catecholaminergic VT-related mutations; once identified silent carriers may be treated with beta-blockers to reduce the risk of cardiac events and may receive appropriate genetic counseling to assess the risk of transmitting the disease to offspring."

Brugada Syndrome:

"Genetic analysis may help identify silent carriers of Brugada syndrome-related mutations so that they can remain under clinical monitoring to detect early manifestations of the syndrome. Furthermore, once identified, silent mutation carriers should receive genetic counseling and discuss the risk of transmitting the disease to offspring."

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