Assessing Genomic Sequencing Information for Health Care Decision Making: Reimbursement Decisions

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The Aetna Way

Our Cause

To make quality health care more affordable and more accessible

Our Strategy

To be the global leader in empowering people to live healthier lives

aetna SM

Overview

We will discuss the following issues:

- The purposes and goals of clinical policy at Aetna
- The criteria Aetna uses to evaluate medical technologies and treatments including genomic sequencing information
- Aetna's clinical policy development process
- Effectiveness guidance documents and genomic sequencing

Clinical Policy Unit Function

- Aetna's Clinical Policy Unit is responsible for evaluating medical technologies to determine whether they are "experimental and investigational" and "medically necessary" as defined in applicable coverage documents
- Aetna has developed more than 700 Clinical Policy Bulletins (CPBs).
- The goal is to develop objective, clinically supported and defensible determinations.

Clinical Coverage Criteria

The following criteria are considered in evaluating a medical technology:

- The technology must have final approval from the appropriate governmental regulatory bodies, when required
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes
- The technology must improve net health outcome
- The technology must be as beneficial as any established alternatives
- The improvement must be attainable outside investigational settings

Prioritizing CPB Requests

The following factors are considered in prioritizing requests for developing CPBs:

- The quantity and importance of questions that have arisen regarding the medical technology
- New evidence, guidelines, consensus statements, changes in regulatory status or other information that is material to the status of the medical technology
- The potential impact of the technology on Aetna and its members

Drafting Clinical Policy Bulletins

The Clinical Policy Unit conducts a comprehensive search of the peer-reviewed published medical literature:

- Search National Library of Medicine's PubMed database of peer-reviewed medical literature
- Assess regulatory status of technology
- Review evidence-based clinical practice guidelines in AHRQ's National Guideline Clearinghouse database
- For oncology diagnostics, Aetna considers the indications from ASCO and from NCCN
- Review technology assessments indexed in NLM's Health Services/Technology Assessment Text (HSTAT) database
- Opinions of relevant experts may be solicited where necessary

CPB Approval Process

- The draft CPB is reviewed and approved by the Clinical Policy Council
- Review by head of Aetna's National Medical Policy and Operations Department
- Review by Aetna's Legal Department
- Review and approval by Aetna's Chief Medical Officer or his designee
- Members of the Clinical Policy Unit work with persons from coding and reimbursement areas (Medical Policy and Operations) regarding implementation of clinical policies in Aetna systems

Annual Review of CPBs

- Clinical Policy Unit conducts comprehensive review of peer-reviewed published medical literature to determine if new information has emerged that may warrant a revision in policy.
- All CPBs are reviewed annually by Aetna's Clinical Policy Council.
- CPB review schedule is posted on the internet.

Specialty Society Policy Liaison Group

Aetna's Specialty Society Policy Liaison Group meets monthly to identify issues for medical specialty society input

- Issues involving clinical policy and coding are discussed and the relevant specialty society is identified
- Aetna medical directors have been assigned to be liaison's for leading medical specialty societies; these medical directors are responsible for soliciting feedback from their designated specialty society
- Specialty society feedback is tracked and the input is considered by Aetna's clinical policy and reimbursement areas

Effectiveness guidance documents (EGDs)

- The purpose of an EGD is to provide guidance to payers, guideline developers and other policymakers on the type of studies necessary to provide reliable evidence of the effectiveness and safety of medical technologies for specific diseases

EGD on Next Gen Sequencing

- The Center for Medical Technology Policy (CMTP) is developing an effectiveness guidance document (EGD) on evidence standards for next generation sequencing-based testing in oncology
- This EGD will be informed by CMTP's recently issued EGD on evidentiary standards for studies of the clinical validity and clinical utility of molecular diagnostics in oncology.

MolDx EGD Recommendations

The CMTP MolDx EGD recommends the following:

- Follow standard reporting guidelines to document analytic validity
- Study patient population intended for test
- Choose appropriate metrics for clinical validation
- Anticipate clinical pathways related to test use
- Select outcomes to measure net patient benefit

Molecular Diagnostic Study Designs

The MolDx EGD recommends the following study designs:

- Randomized controlled trial (RCT) design selection
- Prospective-retrospective study
- Single-arm study
- Prospective observational study
- Modeling techniques (e.g., decision-analytic)

Examples

- Sequencing-based tests to determine fetal aneuploidy from maternal cell-free DNA
- Genomic sequencing for diagnosis of persons with suspected genetic disorders

Questions & Discussion