The Commonwealth of Massachusetts
Health Policy Commission
Office of Patient Protection
Two Boylston Street
Boston, MA 02116

To: External Review Agencies under Contract with the Health Policy Commission Pursuant to G.L. c. 176O, § 14
cc: Commercial Health Insurers, Blue Cross Blue Shield of Massachusetts, and Health Maintenance Organizations Accredited Pursuant to G.L. c. 176O
From: Jenifer Bosco, Director, Office of Patient Protection
Re: Review of Services Considered to be Experimental or Investigational
Date: August 14, 2013

REVIEW OF SERVICES CONSIDERED TO BE EXPERIMENTAL OR INVESTIGATIONAL

Update to Massachusetts Law

Massachusetts law was recently amended to clarify that consumers may seek internal and external reviews of adverse determinations where the carrier has determined that the requested or recommended health care service or treatment is experimental or investigational. See Chapter 35 of the Acts of 2013, Section 56, amending G.L. c. 176O, § 1 (effective date Jan. 1, 2014). This is a clarification of existing Massachusetts policy as implemented by the Office of Patient Protection (OPP). Prior to the effective date of the new law, OPP will continue to implement Massachusetts policy which currently allows for internal and external review of adverse determinations regarding treatment or services considered to be experimental or investigational.

Process for External Review of Services Considered to be Experimental or Investigational

1) Three-Reviewer Panel

In cases involving experimental or investigational treatment, OPP will direct that external review requests be reviewed by a three-reviewer panel assigned by the external review agency (ERA).

2) Medical Necessity Determination

The reviewers shall determine whether the care is medically necessary under Massachusetts law. As in all external review cases, reviewers shall use the following Massachusetts medical necessity standard, and shall include in their written decisions the medical necessity standard and an analysis of why it was or was not met.

"Medical Necessity or Medically Necessary means health care services that are consistent with generally accepted principles of professional medical practice as determined by whether the service:

(1) is the most appropriate available supply or level of service for the insured in question considering potential benefits and harms to the individual;
(2) is known to be effective, based on scientific evidence, professional standards and expert opinion, in improving health outcomes; or
(3) for services and interventions not in widespread use, is based on scientific evidence."

958 CMR 3.020.

External Review Agency Written Decisions

For decisions that involve services denied by the health plan as experimental or investigational, the reviewer must cite reliable evidence to support the decision. Reliable evidence is defined here as one or more of the following regarding the effectiveness and efficacy of the proposed treatment:

- Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not a part of the editorial staff;
- Peer-reviewed literature, biomedical compendia, and other medical literature that meet the criteria of the National Institute of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus (EMBASE), MEDLINE, MEDLARS, Health Services Technology Assessment Texts (HSTAT), or comparable criteria;
- Medical journals recognized by the Secretary of Health and Human Services, under Section 1861(t)(2) of the Social Security Act;
- The following standard reference compendia: The American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopoeia;
- Findings, studies and research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the United States Department of Health and Human Services, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, National Cancer Institute, National Academy of Sciences, National Institutes of Health, and any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services; and
- Any other medical or scientific evidence that is comparable to those listed above.

Medical or scientific evidence shall not include published peer-reviewed literature sponsored to a significant extent by a pharmaceutical or medical device manufacturer.

In cases where an appellant is seeking a retrospective review of already-provided services, reviewers must pay close attention to the date on which the services were rendered. Reviewers should not rely on evidence that was not published or was otherwise unavailable on the date the service was rendered.

OPP recognizes that in certain instances involving extremely rare conditions, there may not be any reliable evidence as defined above regarding proposed treatments. In those instances, the reviewer must cite medical or scientific evidence to support his or her decision.

In keeping with prior OPP guidance, decisions by an ERA must be consistent. ERAs must review decisions regarding same or similar requests and validate the consistency of decisions from reviewer to reviewer. An ERA should not release a decision without checking previous cases for similarities. When two reviewers or review panels come to opposite conclusions, the ERA must be prepared to reconcile the cases to OPP and to the health plans, either by clearly distinguishing the presenting facts of each case or by documenting a change in the supporting evidence. If there is a change in a determination regarding the experimental or investigational status of a particular service, the ERA must support the change with evidence cited above.