

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 240.000: CRITERIA FOR INSURANCE COVERAGE OF BONE MARROW TRANSPLANTS FOR BREAST CANCER PATIENTS

Section

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240.001: Purpose

105 CMR 240.000 establishes criteria for determining whether certain health care providers and insurers will be required under St. 1993, c. 458 to provide coverage for bone marrow transplants for breast cancer patients. Nothing in 105 CMR 240.000 shall be interpreted as preventing a health care provider or insurer covered by 105 CMR 240.000 from providing additional coverage for bone marrow transplants for breast cancer patients where appropriate under eligibility criteria established by the health care provider or insurer.

240.002: Authority

105 CMR 240.000 is promulgated pursuant to St. 1993, c. 458 and M.G.L. c. 111, § 5.

240.003: Scope

105 CMR 240.000 applies to breast cancer patients with insurance coverage provided under one of the following:

- (A) an individual policy of accident and sickness insurance issued pursuant to M.G.L. c. 175, § 108;
- (B) a group blanket policy of accident and sickness insurance issued pursuant to M.G.L. c. 175, § 110;
- (C) a contract between a subscriber and corporation under an individual or group hospital service plan delivered, issued or renewed pursuant to M.G.L. c. 176A, for all individual subscribers or members within the Commonwealth and all group members having a principal place of employment within the Commonwealth;
- (D) a subscription certificate under an individual or group medical service contract delivered, issued or renewed pursuant to M.G.L. c. 176B, for all individual subscribers or members within the Commonwealth and all group members having a principal place of employment within the Commonwealth;
- (E) a group health maintenance contract under M.G.L. c. 176G;
- (F) a plan for any active or retired employee of the Commonwealth offered by the Group Insurance Commission pursuant to M.G.L. c. 32A.

240.004: Definitions

Metastatic disease, for purposes of 105 CMR 240.000, shall mean Stage III and Stage IV breast cancer, as well as Stage II breast cancer which has spread to ten or more lymph nodes, as defined by the American College of Surgeons.

240.004: continued

Bone Marrow Transplant, for purposes of 105 CMR 240.000, shall mean use of high dose chemotherapy and radiation in conjunction with transplantation of autologous bone marrow or peripheral blood stem cells which originate in the bone marrow.

240.005: Insurance Coverage for Eligible Patients

(A) Health care providers, benefits managers and insurers shall work cooperatively with patients with metastatic breast cancer to identify appropriate clinical trials involving the use of bone marrow transplants and provide coverage for bone marrow transplantation, in accordance with the eligibility criteria specified in 105 CMR 240.000. Health care providers or insurers specified in 105 CMR 240.003 who make treatment available through a network of participating providers may use the network to provide bone marrow transplants, in accordance with the requirements of 105 CMR 240.000. If bone marrow transplantation is not available through the network, the health care provider or insurer may arrange and shall provide coverage for a bone marrow transplant meeting the requirements of 105 CMR 240.000.

(B) With respect to patients who have been diagnosed with breast cancer that has progressed to metastatic disease, the health care providers and insurers specified in 105 CMR 240.003 shall:

- (1) permit referral to and participation in clinical trials when an oncologist recommends participation on the grounds that the proposed procedure shows promise as a useful treatment for that patient, and the proposed procedure is likely to be at least as effective as conventional treatment for that patient; and
- (2) provide coverage for a bone marrow transplant, in accordance with 105 CMR 240.005(A), if the patient meets the eligibility criteria for enrollment into a clinical trial meeting the requirements of 105 CMR 240.006, even if the patient is not formally enrolled in that clinical trial;
- (3) provide coverage for a bone marrow transplant to the extent that benefits generally are provided for other medical procedures.

240.006: Suitable Clinical Trials

The health care providers and insurers specified in 105 CMR 240.003 shall provide coverage for bone marrow transplantation, in accordance with 105 CMR 240.000, where the patient has been found to meet the eligibility criteria for a clinical trial satisfying the requirements of 105 CMR 240.006. The clinical trial shall be conducted in accordance with a protocol approved by an institutional review board meeting the requirements for the protection of human subjects specified in 45 CFR Part 46. In addition, the clinical trial shall be conducted:

(A) at a licensed health facility which is located at the principal site of an academic medical center which participates in NCI sponsored or approved research in any cancer specialty area; or

(B) at a licensed health facility which has a formal affiliation agreement with an academic medical center to provide bone marrow transplantation as part of an NCI sponsored or approved research protocol.

240.007: Appeal

Where a breast cancer patient is denied coverage by a health care or insurance provider specified in 105 CMR 240.003, and claims to be eligible for bone marrow transplantation under 105 CMR 240.000, an independent and impartial appeal process shall be made available to the patient.

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240.007: continued

(A) The patient may be required by the health care or insurance provider to exhaust available internal appeals procedures; provided, however, that if the matter is not resolved internally to the patient's satisfaction within 30 days of initiating the appeal, the health care provider or insurer shall refer the matter for final resolution to an impartial and independent review board meeting the requirements of 105 CMR 240.007.

(B) The Department shall establish a list of review boards to which the health provider or insurer may refer an appeal required under 105 CMR 240.007. Review boards may be included in the list if the Department has reason to believe that they will conduct an impartial, independent, fair and timely review of appeals.

(C) If the health provider or insurer utilizes a review board from the Department's list for its own internal appeals process, such review shall satisfy the requirement for an impartial and independent appeal under 105 CMR 240.007.

(D) In the event that the Department is not satisfied with the impartiality, independence, timeliness or fairness of appeals boards seeking to be or already listed, the Department may establish its own appeals board, to be comprised of members of the medical, insurance, and consumer communities.

240.008: Patient Information and Education

The Department of Public Health shall make available to physicians and patients information about options for participation in clinical trials involving bone marrow transplants.

240.009: Advisory Board

The Department shall establish an advisory board, comprised of representatives of the medical, insurance, and consumer communities, to advise the Department on matters pertaining to bone marrow transplants for breast cancer patients. Such advisory board shall meet as often as necessary, but no less than three times a year, in accordance with procedures established by the Department. The advisory board shall advise the Department as to the following:

(A) the desirability, based upon current research and medical data, of amending the eligibility criteria for bone marrow transplants for breast cancer patients established in 105 CMR 240.000. In particular, the advisory board shall advise the Department as to whether there is evidence that bone marrow transplants for a particular stage of cancer not covered by 105 CMR 240.000 shows promise of being a useful treatment for that stage and is likely to be at least as effective as conventional treatment;

(B) the desirability of amending the list developed by the Department of impartial and independent review boards;

(C) the appropriateness of amending the criteria for suitable sites for bone marrow transplantation established in 105 CMR 240.006; and

(D) any matter affecting the implementation of St. 1993, c. 458 or 105 CMR 240.000.

REGULATORY AUTHORITY

105 CMR 240.000: M.G.L. c. 111, § 5; St. 1993, c. 458.

NON-TEXT PAGE