

**3701-84-27 Patient selection/utilization.**

- (A) All candidates for bone marrow transplantation shall be subject to prospective patient selection criteria as specified in appendix A to this rule.
- (B) If a transplantation service desires to perform a transplant on a patient who does not meet the selection protocols set forth in appendix A to this rule, the service shall undertake a thorough review of the case to determine that the transplant is appropriate. This review shall be conducted by a bone marrow transplant team comprised of members of the service's ethics, legal, and medical staff. This review shall, at a minimum, include:
  - (1) Preparation of a detailed clinical summary of the patient including a brief medical history, complete laboratory data, a thorough psychological evaluation including the patient's support system, any psychosocial issues, attitude toward and understanding of the transplant, informed consent, and a justification of the transplant despite failure to meet the selection criteria; and
  - (2) After sufficient review time, an affirmative vote of a majority of the members of the team that the transplant is appropriate.
- (C) Each bone marrow transplantation service should achieve the following volume goals per year to ensure efficiency and a minimum floor of competency:
  - (1) Except as specified in paragraph (C)(2) of this rule, services providing only autologous bone marrow transplantations should perform at least ten per year. From the date a service notifies the director of activation or reactivation of a service, the service should perform at least six transplants in the first twelve months and at least twenty transplants within the first twenty-four months;
  - (2) Services providing only autologous bone marrow transplantation exclusively to patients less than twenty-two years of age should perform at least ten transplants per twenty-four months. From the date this service notifies the director of activation or reactivation of a service, the service should perform at least four transplants in the first twelve months and at least ten transplants within the first twenty-four months;
  - (3) Except as specified in paragraph (C)(4) of this rule, services providing both autologous and allogeneic bone marrow transplantation should perform at least twelve per year with at least six being allogeneic bone marrow transplantations. From the date a service notifies the director of activation or reactivation of a combined autologous and allogeneic service, the service should perform at least eight transplants in the first twelve months and at least twenty-four transplants within the first twenty-four months, of which at least twelve should be allogeneic; and
  - (4) Services providing both autologous and allogeneic bone marrow transplantation exclusively to patients less than twenty-two years of age should perform at least ten transplants per twenty-four months with at least five being allogeneic. From the date this service notifies the director of activation or reactivation of a service, the service should perform at least four transplants in the first twelve months with at least two being allogeneic and at least ten transplants within the first twenty-four months with at least five being allogeneic.

- (D) Volume goals will be considered by the director in conjunction with other indicators of quality, not as the sole indicator of service performance.
- (E) Failure to meet a volume goal for two consecutive years will trigger an extended review of the bone marrow transplantation service by the director, including possible inspections.

Effective: 11/20/2014

Five Year Review (FYR) Dates: 05/01/2017

CERTIFIED ELECTRONICALLY

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Certification

11/10/2014

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Date

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