MDCH Recommendations for CON Standards Scheduled for 2012 Review

Bone Marrow Transplantation (BMT) Services Standards (Please refer to MDCH staff summary of comments for additional details)		
Should services continue to be regulated under CON?	No.	MDCH recommends that the Commission consider deregulating BMT services. BMT is a well established and individualized service and there has been no evidence provided to support concerns regarding either a proliferation of services or a significant increase in treatment numbers.
Identified Issues	**Recommended for Review?**	**Comments**
Review access and expansion throughout the state	Yes.	Consider removing the cap and developing a facility-based need methodology if BMT services are going to remain under CON regulation.
Consider eliminating and/or separating autologous BMT services from the Standards	Yes.	Consider separate requirements if BMT services are going to remain under CON regulation.
Conduct review of project delivery requirements	Yes.	If BMT services are going to remain under CON regulation, update project delivery requirements and make any other technical changes consistent with other CON review standards. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.

MDCH Staff Analysis of Bone Marrow Transplant Services Standards

Statutory Assignment

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "…review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the BMT Services Standards are scheduled for review in calendar year 2012.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 12, 2011, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from seven (7) organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health System*
   - Recommends the removal of BMT services from CON regulation or, at a minimum, mandate an institution specific methodology for BMT or autologous-only BMT.
   - Argues that since 2009, MDCH data shows that demand for BMT has increased in the state of Michigan.
   - Requests the Commission to remove BMT from CON coverage per Section 22215(1) (a) of PA 619.
   - Suggests utilizing the Department or an unbiased consulting group to recommend an institution specific approach for establishing BMT for autologous-only services.

2. *Carol Christner, Karmanos Cancer Center*
   - Supports the standards approved by the Commission less than 18 months ago.
   - States there have been no significant changes in the field of BMT that would warrant revisions to the standards in 2012. Specifically; no significant change to the number of transplants conducted, geographic barriers have been addressed, and there continues to be excess bed capacity.

3. *Dennis McCafftery, Economic Alliance for Michigan (EAM)*
   - Supports continued regulation of BMT services and feels that it is too soon to re-open these standards to consider changes that may result in more providers.
   - Recommends Department-only technical changes, unless there is compelling evidence that would alter autologous only program discussion.
   - Recommends no SAC formation.

4. *Steve Szelag, University of Michigan Health System*
   - Recommends no revisions as capacity in Michigan appears to be adequate and forecasts indicate no drastic change in the number of patients requiring this therapy.
   - Suggests that it is too early to objectively evaluate the effects of the changes approved by the Commission March 2010.

5. *Robert Meeker, Spectrum Health*
   - Supports continued regulation of BMT services and feels that the revisions from March 2010 are serving the state very well.
   - Recommends no modifications at this time.

6. *Sean Gehle, Ascension Health- Michigan*
   - Recommends the separation of Allogenic and Autologolous BMT services.

- Strongly recommends the deregulation of Autologous BMT services within CON.
- States that costs associated with alternative therapies are more expensive than the BMT treatment and follow up treatment.
- States quality related to BMT programs and practitioners is determined and monitored by the Foundation for the Accreditation of Hematopoietic Cellular Therapy (FAHCT).
- States access to BMT should be made available at community cancer centers where earlier treatment of cancer patients has shown to improve survival rates.
- Requests that if the Commission sees a need for continued regulation of Autologous BMT services, that they establish distinct standards applicable for Autologous only BMT programs.

7. *Karen Kippen, Henry Ford Health System*
   - Supports continued regulation of BMT services.
   - Recommends no revisions at this time.

Summary of the Covered Service and Consideration of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need Review"

Currently, Michigan is one of 21 states that regulate organ transplants through CON; less than 10 regulate BMT. There are currently 3 facilities approved to perform these types of transplantation services. In 2008, there were 534 Bone Marrow Transplants performed, 569 in 2009, and 593 in 2010, according to the MDCH annual survey report.

As part of the review, the Department considered the "Guiding Principles…" as follows:

While costs vary widely among facilities, the most recent CON application received for initiation of an adult BMT program (Spectrum Health Butterworth) indicated costs of $499,835. Costs vary from facility to facility, and placing an exact dollar value on operating costs is difficult. As one example, to maintain an up-to-date BMT facility, the University of Michigan (U of M) recently spent $1.5 million to update its stem cell processing lab; $0.5 million to expand tissue typing lab and diagnostic equipment; and $0.5 million for other laboratory equipment. The total costs for expanding and operating BMT services were approximately $8 million for 2008-2009.[1] Looking at operational costs only, U of M expended approximately $5.5 million.

Hematopoietic stem cell transplants are not necessarily the first treatment option for many diagnoses.[2] The most common indications for transplant in the United States in 2009 were multiple myeloma (nearly 5,000 transplants); non-Hodgkin's lymphoma (just over 3,500 transplants); and acute myelogenous leukemia (just under 2,500 transplants). Some non-cancer diagnoses indicate immediate transplant, but these numbered fewer than 1,000 transplants nationwide in 2009.[3]

[1] University of Michigan testimony at February 5, 2009 CON Special Commission Meeting
[2] http://marrow.org/Physicians/When_to_Transplant/Recommended_Timing_for_Transplant_(PDF).aspx
[3] Pasquini MC, Wang Z (2011). Current use and outcome of hematopoietic stem cell transplantation: CIBMTR summary slides, available at: http://www.cibmtr.org

The Foundation for Accreditation of Cellular Therapy (FACT) provides voluntary accreditation to clinical programs and collection and processing facilities. All Michigan BMT programs are FACT accredited. In addition, facilities that manufacture human cell, tissue, and cellular and tissue-based products, including hematopoietic stem cells obtained from peripheral and cord blood, are subject to Title 21 CFR part 1271. However, minimally manipulated bone marrow does not fall under this regulation, instead falling under the authority of the Public Health Service Act, Section 361. Minimal manipulation is defined as "processing that does not alter the relevant biological characteristics of cells or tissues."[4]

BCBS has created Blue Distinction Centers for Transplants that were developed in collaboration with expert physicians and medical organizations, including the Center for International Blood and Marrow Transplant Research (CIBMTR®), the Scientific Registry of Transplant Recipients(SRTR) and the Foundation for the Accreditation of Cellular Therapy (FACT). The selection designation criteria includes: an established transplant program, actively performing these procedures for the most recent 24-month period and performing a required minimum volume of transplant procedures. An established acute care inpatient facility, including intensive care, emergency and a full range of services as well as full accreditation by Centers for Medicare and Medicaid Services (CMS). Quality assurance measures include: evaluation of patient and graft aggregate outcomes including sufficiently low graft failures, mortality rates, a comprehensive quality management program and documented patient care and follow-up procedures at admission and discharge, including referral back to primary care physicians.[5]

CON review standards allow BMT to establish how need will be demonstrated. The 2009 BMT SAC concluded that "Access is somewhat a problem for those living in the farther regions of the state, but…it is impractical to provide access for everyone within a limited travel distance, however that might be defined."[6]

Positive associations have been found between volume and transplant outcome. For example, Horowitz et al. (1992) found that patients receiving transplants in centers that performed fewer than five transplants per year had a 1.5-fold increase in transplant-related mortality risk, and a 1.4-fold increase in treatment failure risk. Similar correlations were found by Apperley et al. (2000) when evaluating center size plus years of experience, and positive associations were replicated in studies of transplant centers in Japan and Europe. However, these studies are insufficient to answer the question of quality's association with volume, as most did not factor in variables such as rate of relapse, staffing, diseases treated, and autologous transplants. It is, therefore, unclear whether a true association exists between volume and quality, or if higher volume centers are simply characterized by variables that indicate more favorable outcomes. Loberiza, Serna, Horowitz, and Rizzo (2003) conclude:

"Based upon current evidence regarding procedure volume, it is not clear that any specific minimum number is justifiable. Restricting procedures to large centers may compromise patient access to HSCT[7] in geographic areas where no large centers exist" (p. 420).[8]

[4] http://www.fda.gov/cber/faq/tisconsfaq.htm
[5] http://www.bcbs.com/why-bcbs/blue-distinction/blue-distinction-transplants/bluedistinctiontransplants.pdf
[6] BMT SAC Report to CON Commission, December 2009
[7] Hematopoietic stem cell transplant
[8] Loberiza F. R., Serna D. S., Horowitz, M. M., & Rizzo, J. D. (2003). Transplant center characteristics and clinical outcomes after hematopoietic stem cell transplant: What do we know. *Bone Marrow Transplantation, 31,* 417-421.

While some aspects of bone marrow transplant saw an increase in CMS reimbursement effective January 1, 2012, other necessary treatment procedures have seen decreases. It is the opinion of the AABB[9] that reimbursement for cellular therapy does not align with the true costs of providing such services.

MDCH Staff Recommendations

- The Department received public testimony supporting the elimination or separation of autologous and allogeneic transplant language from the standards. Autologous treatment represents a smaller capital expenditure and medical research reveals this transplant to be a lower risk option for patients, to deregulate would not lead to perverse incentives or a decline in quality patient care. CMS initially designated DRG 015 as an encompassing code to include all autologous treatments. CMS later determined, this classification did not take into account the severity of complications or comorbidities (CC) that may exist with certain patients. CMS has deleted DRG 015 and separated autologous bone marrow transplants into two classifications: MS-DRG 016 (autologous bone marrow transplant with CC/Major CC) and MS-DRG 017 (autologous bone marrow transplant without CC/Major CC).[10] This will enable CMS to determine accurate reimbursement and monitor the quality of care, taking into account all the assigned diagnoses—not just principal diagnoses.

- These are highly specialized services usually located within university based and/or university affiliated programs or facilities where there is cutting edge technology and ongoing research. In a survey conducted with other CON states, Rhode Island and Virginia stated that they currently have one BMT provider within their state. Neither could identify any applications for initiation of new services, and both stated that the BMT programs were located in university settings.

- The numbers of transplants performed are so few and costs for these procedures are so high that these services are not viable for commercial use. Further, it is CMS's policy to reimburse after a patient receives the transplant. Consequently, if the patient does not receive the transplant due to death or other complications, the diagnostic testing & laboratory processing services associated with bone marrow and peripheral blood progenitor cell transplants are covered only if they are directly and immediately attributable to the stem cell donation procedure.[11]

- The Department recommends that the Commission consider deregulating BMT services. BMT is a well established and individualized service and there has been no evidence provided to support concerns regarding either a proliferation of services or a significant increase in treatment numbers.

[9] Formerly American Association of Blood Banks; now known only as AABB: www.aabb.org
[10] http://www.justcoding.com/274855/cms-makes-several-key-changes-to-msdrgs-for-fy-2012
[11] http://www.aabb.org/programs/reimbursementinitiatives/Pages/default.aspx