MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
BONE MARROW TRANSPLANTATION SERVICES
STANDARD ADVISORY COMMITTEE (BMTSAC) MEETING

Thursday, February 11, 2016

Grand Tower Building
235 S. Grand Ave.
Lansing, Michigan 48933

APPROVED MINUTES

I. Call to Order and Introductions

Chairperson Carl called the meeting to order at 1:03 p.m.

A. Members Present:

Muneer Abidi, MD, Spectrum Health Hospitals
Adil Akhtar, MD, Beaumont Hospitals
Jennifer Barish, BMT Link Network
Bruce Carl, MD, Chairperson, UAW Retiree Benefits Trust
Roland Chu, MD, Children's Hospital of Michigan
Joan Herbert, PharmD, MidMichigan Health
Feroze Momin, MD, Oakwood Hospital- Dearborn
Edward Peres, MD, Henry Ford Health Systems
Joseph Uberti, MD PhD, Barbara Ann Karmanos Cancer Institute
Michael Wiemann, MD, St. John Providence
Felicia Williams, MD, BCBSM/BCN
Gregory Yanik, MD, University of Michigan Health System

B. Members Absent:

None

C. Department Staff Present:

Tulika Bhattacharya
Sallie Flanders
Amber Myers
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

None.

III. Review of Agenda

Motion by Dr. Abidi, seconded by Dr. Peres, to accept the agenda as presented. Motion Carried.

IV. Review of Minutes from January 14, 2016

Motion by Dr. Uberti, seconded by Dr. Herbert, to accept the minutes as presented.

V. Presentation on Beaumont's Proposed Methodology

Dr. Akhtar presented a proposed methodology (see Attachment A).

Discussion followed.

Recessed at 2:11 p.m. and reconvened at 2:25 p.m.

VI. Review and Discussion of Charge 3 and Completion of Grid

Chairperson Carl reviewed Charge 3. Discussion and completion of grid (see Attachment B) followed.

Motion by Ms. Barish, seconded by Dr. Yanik, to have the Department send the methodology presented today to Dr. Paul Delamater to evaluate this methodology and provide input on other methodology options. Motion Carried in a vote of 12 - Yes, 0 - No, and 0 - Abstained.

VII. Next Steps

Chairperson Carl asked that any material for the next meeting be submitted to the Department for distribution to the SAC.

Chairperson Carl told the SAC that the grids completed at this and the previous meeting would be sent out to the SAC for review.

VIII. Future Meeting Dates - March 10, 2016; April 7, 2016; May 12, 2016

IX. Public Comment

None.

X. Adjournment

Motion by Dr. Yanik, seconded by Dr. Uberti, to adjourn the meeting at 3:55 p.m. Motion Carried.

BMT Need Methodology

BMT SAC

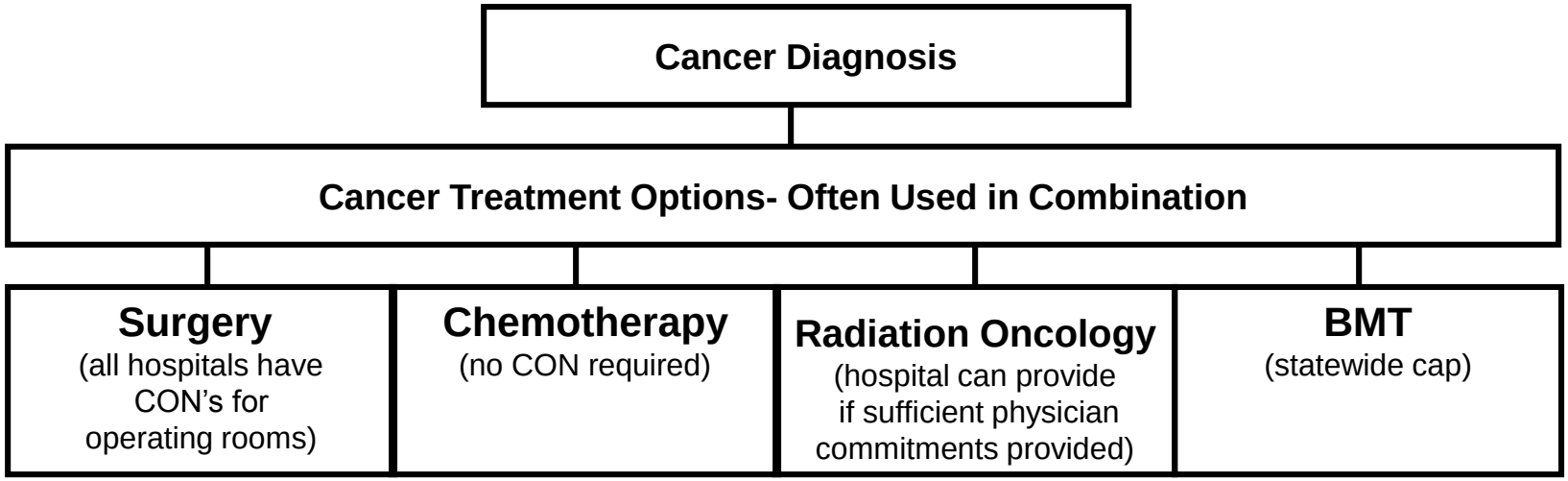
February 11, 2016

Overview

Attachment A

- SAC has voted to continue CON regulation of BMT (Charges 1 & 2)
- SAC must now recommend a CON need methodology for BMT (Charge 3)
  - Recommended methodology must take into account “consistency of CON approach” between BMT and other CON covered services (Charge 4)
  - CON trend in Michigan has been toward institution-specific methodologies (vs. caps)

BMT is the Only Cancer Treatment Option with Program Limit



Consistency of CON Approach to Need

PET*	**based on**	**tumor registry cases**
ESWL*	**based on**	**urological discharges**
Open heart	**based on**	**cardiac discharges**
Radiation oncology	**based on**	**physician commitments**
BMT	**based on**	**cap**

*Cap removed in favor of institution specific need methodology

Attachment A

Proposed BMT Methodology

- Starts with Statewide Tumor Registry Cases for cancers for patients age 20+ most often requiring BMT (sources: Michigan Cancer Surveillance Program; Centers for Disease Control & Prevention)
- Each “cancer category” is multiplied by a “factor” (percentage) of cases likely to result in BMT. For the “base year” (2012- most recently available statewide tumor registry data), the factor is calculated by dividing the total Statewide BMT cases (from the Michigan Inpatient Data Base) by the Statewide Tumor Registry Cases.
  - This need methodology is very conservative because it does not take into account unmet need- the total “need” for the State is simply the total number of BMT’s performed.

BMT Need Methodology
Calculation of Factors (2012)

Attachment A

(A) Diagnosis	(B) 2012 State Registry Cases*	(C) Factor (Estimated % receiving BMT)***	(D) 2012 Statewide Volume**
Non-Hodgkins	2197	5.5%	121
Hodgkins	238	11.7%	28
Acute Leukemia (ALL/ AML)	515	21.6%	111
Chronic Leukemia (CML)	178	4.5%	8
Multiple Myeloma	702	27.1%	191
Myelodysplastic Syndrome	519	6.2%	32
Other	629	3.6%	23
Total	4978	10.3%	514

* Source: Michigan Cancer Surveillance Program; Centers for Disease Control
** Source: Michigan Inpatient Data Base (totals match closely with CON Annual Survey totals)
*** Calculated Field (D/B)

Proposed BMT Methodology (continued)

Attachment A

- Applicants for a new BMT program demonstrate need by applying their institutional tumor registry cases by cancer category to the corresponding factor, and summing the results. If the summed results meet the (TBD) “threshold”, then the applicant would demonstrate need and could initiate a program.
  - Note: the FACT minimum volumes are 10*; the current BMT CON standard minimum volume is 30
- Applicants using their own tumor registry could combine their cases from other hospitals who agree to “commit” their cases to the applicant (consistent with other CON standards)
- Tumor registry cases at existing hospitals with a BMT program could not be used to support other applications
- Once tumor registry cases from a hospital are committed to an application, those tumor registry cases could not be used again as long as the new program is operational (consistent with other CON standards)
  - This provision limits the number of new programs that can be approved

*Source: Foundation for the Accreditation of Cellular Therapy, FACT-JACIE International Standards for Hematopoietic Cellular Therapy, 6th Edition.

BMT Need Methodology
Calculation of Factor, 2010-2012

Attachment A

(A) Diagnosis	2010 Factor (Estimated % receiving BMT)	2011 Factor (Estimated % receiving BMT)	2012 Factor (Estimated % receiving BMT)
Non-Hodgkins	4.9%	5.3%	5.5%
Hodgkins	14.5%	11.9%	11.7%
Acute Leukemia (ALL/ AML)	19.4%	21.6%	21.6%
Chronic Leukemia (CML)	2.7%	4.5%	4.5%
Multiple Myeloma	25.7%	26.3%	27.1%
Myelodysplastic Syndrome	2.9%	4.9%	6.2%
Other	6.9%	5.1%	3.6%
Total	9.8%	10.3%	10.3%

Conclusions

- Current cap approach is out of date and should be replaced with a rational, data based need methodology (Charges 3, 4)

- BMT methodology presented is consistent with need methodologies for other CON covered services

- Proposed next step is to request the Department to review, validate and make recommendations pertaining to this methodology

How Does Continued CON Regulation of Autologous BMT Services Impact Cost, Quality, and Access either Positively or Negatively?

	Positively	Negatively
Cost	• Standardization for implementing all required standards for facilities already approved and operating a program • Continuity of care - product at the center already if the patient relapses • Reports showing that CON states have lower BMT costs • No proliferation will occur if BMT cap is removed • Large volume facilities can bundle hospital and drug charges	• Start- up costs - facility and personnel • FACT Accreditation • Maintenance costs for maintaining current program • Changing in the field for immuno-based therapies and trials • Compared to other CON services the amount spent on BMT is very low • BMT is often no more costlier than non-CON regulated chemotherapy drugs • Testing is often repeated when patients are referred from one center to another for BMT • No potential for excessive utilization
Quality	• Continuity of Care • Continuing education of staff • Keeping up with the standards as well as the indications of transplant • Specialized physicians and ancillary staff • Existing centers provide high quality care • Transplant care is optimized if provided 24/7 365 by a transplant trained personnel • Volume of transplant patients improves treatment of patients and improves the knowledge and practice of treatment • Outcomes of trials have proven that BMT volume does matter	• Specialization and ancillary staff would become under utilized • More trained personnel in the field • BMT outcomes are not impacted by CON regulations • No correlation between one year survival rates and the BMT volume of the program • BMT quality is being monitored by FACT • Stem cell therapies will be tried in non-cancer indications, limiting programs will limit research • Michigan BMT programs have better than national average outcomes • FACT accreditation is not a means of licensing and does not recognize outcomes • Poor patient selection and unnecessary fixed costs to purchasers in non-CON covered states

How Does Continued CON Regulation of Autologous BMT Services Impact Cost, Quality, and Access either Positively or Negatively?

Access	• No issues with access and capacity is in fact underutilized, including southeast and northern Michigan • Adding new centers will not improve access • Access is determined by issues other than center location including socio-economic and other demographic factors • Patients don't want convenient care - they want optimal care • Adding programs will not address the barriers already affecting access	• Hard to quantitate access • Patient preference • Excess capacity does not equal access • Unmet need for BMT • Volume of the transplant continues to increase • Timely referral of patients for transplant, especially minority populations who continue to be under served

How Does Continued CON Regulation of Allogeneic BMT Services Impact Cost, Quality, and Access either Positively or Negatively?

Cost

Positively	Negatively
• Standardization for implementing all required standards for facilities already approved and operating a program • Continuity of care- product at the center already of the patient relapses • Reports showing that CON states have lower BMT costs • No proliferation will occur if BMT cap is removed • Large volume facilities can bundle hospital and drug charges • **Complexity of treatment** • **Donor issues** • **Cost of developing and maintaining an HLA lab and molecular diagnostic** • **More programs will increase costs to consumers** • **Transplant related costs will increase if BMT is deregulated due to outbidding of staff and capital costs of new programs**	• Start- up costs- facility and personnel • FACT Accreditation • Maintenance costs for maintaining current program • Changing in the field for immuno-based therapies and trials • Compared to other CON services the amount spent on BMT is very low • BMT is often no more costlier than non-CON regulated chemotherapy drugs • Testing is often repeated when patients are referred from one center to another for BMT • No potential for excessive utilization

How Does Continued CON Regulation of Allogeneic BMT Services Impact Cost, Quality, and Access either Positively or Negatively?

Quality

• Continuity of Care • Continuing education of staff • Keeping up with the standards as well as the indications of transplant • Specialized physicians and ancillary staff • Existing centers provide high quality care • Transplant care is optimized if provided 24/7 365 by a transplant trained personnel • Volume of transplant patients improves treatment of patients and improves the knowledge and practice of treatment • Outcomes of trials have proven that BMT volume does matter • **There is a shift in healthcare teams regardless if it's from within the same facility** • **In addition to competent BMT staff, a program requires access to specialized consultative services that are familiar with BMT related complications** • **As more BMT patients are alive, long term follow up care provided by the BMT team along with the community physicians is extremely important**	• Specialization and ancillary staff would become under utilized • More trained personnel in the field • BMT outcomes are not impacted by CON regulations • No correlation between one year survival rates and the BMT volume of the program • BMT quality is being monitored by FACT • Stem cell therapies will be tried in non-cancer indications, limiting programs will limit research • Michigan BMT programs have better than national average outcomes • FACT accreditation is not a means of licensing and does not recognize outcomes • Poor patient selection and unnecessary fixed costs to purchasers in non-CON covered states • **Non-BMT intense cancer treatments are being done in other healthcare systems so why not BMT**

How Does Continued CON Regulation of Allogeneic BMT Services Impact Cost, Quality, and Access either Positively or Negatively?

Access

• No issues with access and capacity is in fact underutilized, including southeast and northern Michigan • Adding new centers will not improve access • Access is determined by issues other than center location including socio-economic and other demographic factors • Patients don't want convenient care they want optimal care • Adding programs will not address the barriers already affecting access • **Patient has to spend more time at the center after they undergo the transplant** • **Geographic access in Michigan is better than most states in the US**	• Hard to quantitate access • Patient preference • Excess capacity does not equal access • Unmet need for BMT • Volume of the transplant continues to increase • Timely referral of patients for transplant, especially minority populations who continue to be under served • **Patients are looking for convenience of care with optimal care** • **Large healthcare systems with large patient volume should not have to displace their patients from their primary area of residence and primary care teams**