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

Thursday, October 22, 2009

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call to Order

Chairperson VeCasey called the meeting to order at 9:10 a.m.

A. Members Present:

Paul Adams, MD, Vice-Chairperson, Self (left at 12:15 a.m.)
Aly Abdel-Mageed, MD, Spectrum Health
Adil Akhtar, MD, Beaumont Hospitals (via conference call from 9:13 – 10:45 a.m.)
Nalini Janakiraman, MD, Henry Ford Health System
Mary Marks, Alliance for Health
Thomas Ruane, MD, Blue Cross Blue Shield/Blue Care Network
Samuel Silver, MD, University of Michigan Health System
Joseph Uberti, MD PhD, Barbara Ann Karmanos Cancer Institute
Donald VeCasey, Chairperson, Consumer Health Care Coalitiion

B. Members Absent:

Grant Grace, UAW
Elna Saah, MD, Michigan State University
Jeffrey Trent, PhD, VanAndel Research Institute
Amy Vanderwoude, MD, Cancer & Hematology Centers of West Michigan
Michael Wiemann, MD FACP, St. John Health System

C. Michigan Department of Community Health Staff Present:

Jessica Austin
Michael Berrios
Sallie Flanders
Kasi Kelley
Andrea Moore
Brenda Rogers

Chairperson VeCasey had members of the SAC introduce themselves.

II. Declaration of Conflicts of Interests

No conflicts were noted for the record.

III. Review of Agenda

Ms. Marks requested that a discussion of possible revision of the minimum volume requirements within Section 3 be added to the agenda after Item V.

Motion by Dr. Adams, seconded by Ms. Marks to accept the agenda as modified. Motion Carried.

IV. Review of Minutes August 28, 2009

Motion by Dr. Ruane, seconded by Dr. Silver, to accept the minutes as presented. Motion Carried.

V. Comparative Review and Project Delivery Requirements

Dr. Abdel-Mageed provided a presentation on the proposed changes to the Standards (Attachment A) and draft language (Attachment B). Discussion followed.

Break from 10:45 a.m. to 11:03 a.m.

Discussion continued on the comparative review criteria. The committee agreed to remove the infectious disease criteria from the comparative review criteria.

Motion by Dr. Abdel-Mageed, seconded by Dr. Uberti, to approve the modifications to the comparative review as discussed. Motion Carried.

Public Comment:

Robert Meeker, Spectrum Health

Discussion on the project delivery requirements followed.

VI. Minimum Volume Requirements

Ms. Marks provided draft language to modify the minimum volume requirements (Attachment C).

Public Comment:

Dennis McCafferty, Economic Alliance of Michigan

Discussion followed.

Motion by Ms. Marks, seconded by Dr. Ruane to modify the minimum volume requirements as presented. Motion Failed.

Discussion continued regarding Section 7.

Public Comment:

Robert Meeker, Spectrum Health

VII. Final Review of SAC Activities

Chairperson VeCasey gave an overview of the status of each Charge item. Discussion followed.

VIII. Public Comment

None.

IX. Future Meeting Dates

November 18, 2009

X. Adjournment

Meeting adjourned due to loss of quorum at 12:15 p.m. Motion Carried.

SPECTRUM HEALTH

Attachment A

SPECTRUM HEALTH

Bone Marrow Transplant CON Standards

Proposed Revisions to Project Delivery Requirements and Comparative Review Standards

Aly S. Abdel-Mageed, MD

Division Chief, Pediatric Blood and Marrow Transplant Program

Helen DeVos Children's Hospital

SPECTRUM HEALTH

Proposed Project Delivery Requirements

Separate from list of physician specialists those requiring special training/experience in transplant services

Specify that the transplant team coordinator should have experience in evaluating pre- and post-transplant patients

SPECTRUM HEALTH

Existing Comparative Review Standards

Number of BMT programs in the HSA

Indigent care volume

Experience providing pre- and post-transplant care

SPECTRUM HEALTH

Proposed Comparative Review Standards

Replace HSA criterion with a distance standard (2 points)

Retain indigent care criterion (4 points)

Retain criterion of experience with pre- and post BMT patients (2 points)

Add standard acknowledging availability of necessary support services and personnel (11 points)

Add standard reflecting quality of existing hospital services (2points)

SPECTRUM HEALTH

Proposed Distance Standard

Straight-line distance to nearest BMT program	Points Awarded
< 75 miles	0
75 – 150 miles	1
> 150 miles	2

SPECTRUM HEALTH

Proposed Standard for Availability of Support Services

One point for each of the following support services

- Cytogenetics/molecular genetics laboratory
- Cryo-preservation laboratory
- Histocompatibility laboratory
- Clinical pathologist experienced in BMT/GVH related pathologies
- Therapeutic drug monitoring
- Specified physician specialties with transplant experience
- Transplant team coordinator
- Nurses with specialized training
- Clinical pharmacist with BMT experience
- Protective environment for immuno-suppressed patients
- An active multi-disciplinary research program

SPECTRUM HEALTH

Proposed Quality Standard

Proposed quality measures:

- **Number of central line associated bloodstream infections per 1000 central line days**
- **Number of ventilator associated pneumonia infections per 1000 ventilator days.**

For each of these measures:

Highest infection rate	0 points
“Middle” infection rates	1 points
Lowest infection rate	2 points

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Questions?

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MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR BONE MARROW TRANSPLANTATION SERVICES

Excerpts
Suggested Revisions:
Comparative Review Criteria
and
Project Delivery Requirements

Section 4. Additional requirements for applications included in comparative reviews

Sec. 4. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or these standards, shall be grouped and reviewed with other applications in accordance with the CON rules applicable to comparative reviews.

~~(2)(a) A qualifying project will have points awarded based on the number of bone marrow transplantation services, adult or pediatric, as applicable, listed on the Department inventory in the health service area in which the proposed service will be located, on the date the application is submitted to the Department, as shown in the following schedule:~~

~~Number of BMT Transplant Services in HSA (adult or pediatric, as applicable)~~	~~Points Awarded~~
~~Two or more services~~	~~0~~
~~One service~~	~~2~~
~~No services~~	~~4~~

2(a) A qualifying project will have points awarded based on the straight-line distance to the nearest existing BMT program of the type applied for (adult or pediatric), as shown in the following schedule:

Straight-line distance to nearest BMT program	Points Awarded
< 75 miles	0
75 – 150 miles	1
> 150 miles	2

(b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed hospital site at which the proposed bone marrow transplantation service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume, rounded to the nearest whole number, for each licensed hospital site at which a bone marrow transplantation service is proposed to be provided. Determine the licensed hospital site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed hospital site by 4.0. The result is the indigent volume factor.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the first decimal place, is the number of points that will be awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Michigan Department of Community Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Program Hospital Manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(c) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the bone marrow transplant procedures will be performed and were referred for and received a bone marrow transplant at an existing bone marrow transplantation service, and submits documentation from the existing bone marrow transplantation service(s) of these referrals.

(d) A qualifying project will have points awarded based on the number of necessary support services/personnel identified in Sec. 6 which the applicant has available onsite on the date the application is submitted to the Department. The applicant shall one (1) point each, up to a maximum of eleven (11) points, for compliance with the following sub paragraphs: 6(1)(c)(i)(B); 6(1)(c)(i)(C); 6(1)(c)(i)(D); 6(1)(c)(i)(E); 6(1)(c)(i)(F); 6(1)(c)(ii)(A); 6(1)(c)(iv)(D); 6(1)(c)(iv)(E); 6(1)(c)(iv)(G); 6(1)(c)(iv)(H); and 6(1)(c)(x).

(e) A qualifying project will have up to 2 points awarded based hospital wide infection rates, using each of the following measures:

1. **Number of central line associated bloodstream infections per 1000 central line days**
2. **Number of ventilator associated pneumonia infections per 1000 ventilator days.**

For each of these measures, the applicant with the best (lowest) infection rate will receive 2 points. The applicant with the worst (highest) rate will receive no points. All applicants with rates between the highest and lowest receive 1 point each.

(3) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, and which have the highest number of points when the results of subsection (2) are totaled. If two or more

qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, when taken together, do not exceed the need, in the order in which the applications were received by the Department, based on the date and time stamp placed on the applications by the Department in accordance with Rule 325.9123.

(4) No points will be awarded to an applicant under specific subsections of Section 4 if information presented is inconsistent with related information provided in other portions of the CON application. CON Review Standards for Bone Marrow Transplantation Services CON-229 Approved 9/16/08 Effective 11/13/08 Page 7 of 13

Section 6. Project delivery requirements -- terms of approval for all applicants

Sec. 6. (1) An applicant shall agree that, if approved, the bone marrow transplantation service shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the bone marrow transplantation service that may affect its ability to comply with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards, as applicable, no later than the date the first bone marrow transplant procedure, allogeneic or autologous, is performed:

(i) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:

(A) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(B) a cytogenetics and/or molecular genetic laboratory.

(C) a processing and cryopreservation laboratory that meets the standards of the Foundation for Accreditation of Cell Therapy (FACT) or an equivalent organization.

(D) for a program that performs allogeneic transplants, a histocompatibility laboratory that has the capability of DNA-based HLA-typing and meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(E) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in immuno-compromised hosts (programs performing allogeneic or autologous transplants).

(F) therapeutic drug monitoring.

(ii) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:

(A) a protective environmental bone marrow transplant inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

(B) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.

(iii) An applicant shall establish and maintain written policies related to outpatient care for bone marrow transplantation patients, including at least the following:

(A) the ability to evaluate and provide treatment on a 24-hour basis.

(B) nurses experienced in the care of bone marrow transplantation patients.

(C) a designated outpatient area for patients requiring long-duration infusions or the administration of multiple medications or blood product transfusions.

(iv) A bone marrow transplantation service shall establish and maintain a dedicated transplant team that includes at least the following staff:

(A) a transplant team leader, who is a physician that is board-certified in at least one of the following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate, and has had either at least one year of specific clinical training or two years of experience, both inpatient and outpatient, as an attending physician principally responsible for the clinical management of patients treated with hematopoietic transplantation. If the bone marrow transplantation service performs allogeneic transplants, the team leader's experience shall include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the medical care provided by attending physicians, reporting required data to the Department, and responsibility for ensuring compliance with the all applicable project delivery requirements.

(B) one or more attending physicians with specialized training in pediatric and/or adult, as appropriate, bone marrow transplantation. If a service performs allogeneic transplants, at least one attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.

(C) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric, as appropriate, in at least the following specialities: ~~anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic or autologous transplants),~~ cardiology, gastroenterology, ~~infectious diseases with experience in immuno-compromised hosts,~~ nephrology, psychiatry, pulmonary medicine, and critical care medicine.~~, and radiation oncology with experience in total body irradiation, and an intensivist who is board-certified in critical care.~~

(D) on-site availability of board-certified or board-eligible consulting physicians in the following areas: anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic or autologous transplants), infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience in total body irradiation,

(E~~D~~) a transplant team coordinator, with experience in evaluating pre and post transplant patients, who shall be responsible for providing pre-transplant patient evaluation and coordinating treatment and post-transplant follow-up and care.

(F~~E~~) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical status.

(G~~F~~) nurses with specialized training in pediatric and/or adult, as appropriate, bone marrow transplantation, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with compromised host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(H~~G~~) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

(I~~H~~) dietary staff capable of providing dietary consultations regarding a patient's nutritional status, including total parenteral nutrition.

(J~~I~~) designated social services staff.

(K~~J~~) designated physical therapy staff.

(L~~K~~) data management personnel designated to the bone marrow transplantation service.

(M~~L~~) for an applicant performing pediatric bone marrow transplants, a child-life specialist.

(v) In addition to the dedicated transplant team required in subdivision (iv), an applicant's staff shall include a patient ombudsman, who is familiar with the bone marrow transplantation service, but who is not a member of the transplant team.

(vi) An applicant shall develop and maintain patient management plans and protocols that include the following:

(A) therapeutic and evaluative procedures for the acute and long-term management of a patient.

(B) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the service.

(C) long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for at least 5 years.

(D) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-approved clinical research protocol, written policies and procedures that include at least the following: donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative regimen, post-transplantation care, prevention and treatment of graft-versus-host disease (allogeneic transplants), and follow-up care.

(vii) An applicant shall establish and maintain a written quality assurance plan.

(viii) An applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(ix) An applicant shall participate actively in the education of the general public and the medical community with regard to bone marrow transplantation, and make donation literature available in public areas of the institution.

(x) An applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed bone marrow transplantation service.

(xi) An applicant shall operate, either on-site or under its direct control, a multi-disciplinary selection committee which includes, but is not limited to, a social worker, a mental health professional, and physicians experienced in treating bone marrow transplant patients.

(xii) A pediatric bone marrow transplant service shall maintain membership status in the Children’s Oncology Group (COG).

(xiii) For purposes of evaluating subsection (c), except subdivision (xii), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant documents that the bone marrow transplantation service is accredited by the National Marrow Donor Program (NMDP) or the Foundation for the Accreditation of Cell Therapy (FACT).

(xiv) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(d) Compliance with the following terms of approval:

(i) An applicant shall perform the applicable required volumes as follow:

(A) An adult bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. If an adult service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 adult transplants in any 36-month consecutive period, with no fewer than 5 allogeneic in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(B) A pediatric bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. If a pediatric service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in

any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(C) A bone marrow transplantation service that performs both adult and pediatric bone marrow transplants shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.

(ii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; in a format established by the Department; and in a mutually-agreed upon media. The Department may elect to verify the data through on-site review of appropriate records. In addition, an applicant shall report at least the following data for each patient:

(A) disease type.

(B) transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous.

(C) source of hematopoietic stem cell, i.e., bone marrow, peripheral circulation, cord blood, etc.

(D) patient age, i.e., adult or pediatric as defined by these standards.

(E) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.

(F) relapse rates at 6-months, 1-year, and 5-years post-transplant.

(G) median follow-up, and patients lost-to-followup.

(H) cause(s) of death, if applicable.

(I) additional summary information, as applicable.

An applicant annually shall report for its bone marrow transplantation service annual and cumulative survival rates by type of transplant performed reported in actual number of transplants by disease category, transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous; source of hematopoietic stem cell; patient age, i.e., adult or pediatric, as defined by these standards; and relapse rates at 100-days, 6-months, one year, and five years post-transplant. For purposes of these standards, procedure-related mortality is defined as death occurring within 100 days from bone marrow transplant.

(iii) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall participate in the national and international registries applicable to the bone marrow transplantation service.

(iv) An applicant, to assure that the bone marrow transplantation service(s) will be utilized by all segments of the Michigan population, shall:

(A) not deny the services to any individual based on ability to pay or source of payment;

(B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; and

(C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(v) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules. An applicant that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform either allogeneic or autologous procedures, whichever was not performed initially by the applicant.

(vi) An applicant shall notify the Department immediately if the consulting agreement required pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of operation of the bone marrow transplantation service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.

(vii) The Department may use the information provided pursuant to Section 3(10) of these standards in evaluating compliance with the requirements of this section.

(2) The agreements and assurances required by this section, as applicable, shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 3. Requirements for approval for applicants proposing to initiate a bone marrow transplantation service

(6)(a) An applicant proposing to initiate an adult bone marrow transplantation service ~~that will perform only allogeneic transplants, or both allogeneic and autologous transplants~~, shall project that at least ~~10~~ **30 TRANSPLANTS, OF WHICH AT LEAST 10 ARE** allogeneic transplant procedures will be performed in the third 12-months of operation. ~~An applicant proposing to initiate an adult bone marrow transplantation service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.~~

(b) An applicant proposing to initiate a pediatric bone marrow transplantation ~~service that will perform only allogeneic transplants, or both allogeneic and autologous transplants~~, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation~~. An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.~~

Section 6. Project delivery requirements -- terms of approval for all applicants

(d) Compliance with the following terms of approval:

(i) An applicant shall perform the applicable required volumes as follow:

(A) An adult bone marrow transplantation service ~~that performs only allogeneic transplants, or both allogeneic and autologous transplants~~, shall perform at least ~~10~~ **30 TRANSPLANTS, OF WHICH AT LEAST 10 ARE** allogeneic transplants in the third 12-months of operation **AND ANNUALLY**~~. If an adult service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 adult transplants in any 36-month consecutive period, with no fewer than 5 allogeneic in any 12-month period, beginning with the third 12-months of operation, and~~ thereafter.

(B) A pediatric bone marrow transplantation service ~~that performs only allogeneic transplants, or both allogeneic and autologous transplants~~, shall perform at least 10 allogeneic transplants in the third 12-months of operation. ~~If a pediatric service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation.~~ After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants ~~in~~ any 12-month period, beginning with the third 12-months of operation, and thereafter.