

MDCH Recommendations for CON Standards Scheduled for 2012 Review

Pancreas Transplantation Services (Please refer to the attached MDCH staff analysis for additional details)		
Should the covered service continue to be regulated?	No.	The need to regulate does not exist as the procedures continue to decrease with emerging medical technology. Quality-driven programs will continue to thrive as facilities are federally mandated to comply with the Organ Procurement Transplantation Network (OPTN) for Medicare approval to receive reimbursement.
All Identified Issues	Recommended Course of Action to Review Issues	Other/Comments
None.		Recommends no revisions at this time.

MDCH Staff Analysis of the Pancreas Transplantation Services Standards

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 Pancreatic Transplantation 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 four (4) organizations and is summarized as follows:

Patrick O'Donovan, Beaumont Health System

- Supports the continued regulation of pancreas transplantation services.
- Recommends no changes at this time.

Dennis McCafferty, Economic Alliance for Michigan (EAM)

- Supports the continued regulation of pancreas transplantation services.
- States the new standards use the number of kidney transplants performed by an institution as the surrogate for proficiency with pancreas transplants, and revising the standards to allow for additional providers is unnecessary.
- Recommends department-only technical changes without the formation of a SAC.

Steve Szelag, University of Michigan Health System

- Supports the continued regulation of pancreas transplantation services.

- Recommends no revisions at this time, as it is too early to objectively evaluate the effects of the modifications approved in March 2010, and waiting until the next review cycle in 2015.

Karen Kippen, Henry Ford Health System

- Supports the continued regulation of pancreas transplantation services.
- Recommends no changes 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”

Michigan is one of 21 states which regulate Organ Transplantation Standards within CON. According to the CON Annual Survey, there were 26 pancreatic transplantation procedures performed in 2009, and 18 performed within 2010. There are currently three (3) facilities that are approved to provide these services within the State of Michigan.

As part of the review, the Department considered the “Guiding Principles...” as follows:

Pancreas Transplantation Services have low capital costs. According to the most recent CON applications, none of the facilities were close to the covered capital expenditure threshold of \$2,932,500 (2009). The capital costs to initiate this service should remain relatively low because most facilities seeking initiation have existing infrastructure such as: surgical services, pre and post-operative services, staffing & existing Nephrologists and transplant surgeons to support and perform transplant procedures. The Department could not obtain facility specific operating cost information. Since 2009, no applications to establish a new pancreas transplant program have been submitted.

Pancreas Transplantation Services are provided by 3 approved programs in the State of Michigan. The number of these procedures has remained relatively low over the last few years: in 2008 - 26, 2009 - 26 and in 2010 - 18 pancreas transplants; as procedures are constrained to the availability of organ donation.¹ Pancreas allograft acceptance is markedly more selective than other solid organs. The number of pancreata recovered is insufficient to meet the demand for pancreas transplants, particularly for patients awaiting simultaneous kidney-pancreas transplant.² Pancreas Transplant Services are required to be in compliance with Medicare’s requirements in order to be reimbursed for the transplant. The evaluation of a program’s compliance with Medicare requirements involves several steps. CMS will obtain data from United Network for Organ Sharing (UNOS), the contractor for the Organ Procurement Transplantation Network (OPTN), and from the University of Michigan to provide background and determine compliance with the program’s OPTN membership, submission of forms to OPTN, clinical experience (volume), and outcomes, as applicable. CMS will share this information with either the State Survey Agency or CMS’ Contractor (depending upon the provider’s location) to incorporate into their onsite evaluation of compliance with the Medicare Conditions of participation.³

¹ CON Annual Survey Data: 2008, 2009, 2010

² <http://deepblue.lib.umich.edu/bitstream/2027.42/78607/1/j.1600-6143.2009.02996.x.pdf>

³ https://www.cms.gov/CertificationandCompliance/20_Transplant.asp

The current Pancreas Transplantation standards requires an applicant proposing to establish a new service to: project a minimum of 2 pancreas transplantation procedures annually in the second 12 months of operation following the date on which the first pancreas transplant procedure is performed, and has performed a minimum of 80 kidney transplants in the 2 most recent 12 month periods verifiable by the Department. Geographic access to Pancreas Transplantation services is not compromised by CON requirements; this particular service is constrained by the availability of organ donations.

There is a direct relation between quality and volume as is recognized by volume standards associated with federal approvals (e.g. CMS, OPTN). Transplant centers must meet all data submission, clinical experience, and outcome requirements to receive initial approval by CMS, and they must also perform 10 transplants over a 12-month period. The transplant center's Quality Assessment and Performance Improvement (QAPI) program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, and patient education, satisfaction, and rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.⁴

The UNOS By-Laws require Transplant Hospitals to implement and practice appropriate routine referral procedures for all potential donors. Transplant Hospitals are further expected to demonstrate compliance based upon an annual medical record review, performed in collaboration with the OPO. Centers found to be out of compliance will be reviewed by the Membership and Professional Standards Committee.⁵ In addition, this particular service is constrained by the availability of organ donations.

MDCH Staff Recommendations

- Consider de-regulating Pancreas Transplantation Services as the need to regulate does not exist as the procedures continue to decrease due to organ availability. The key factors in the consideration of whether CON regulation is necessary for a covered service is whether the proposed regulation is necessary to assure that health services are of a high quality, provide the public access to needed health services, and are cost beneficial.
- The uses of Pancreas Transplantation Services are a specific medical treatment rather than a diagnostic procedure. Quality-driven programs will continue to thrive as all hospitals in the United States that provide pancreas transplant programs must be a member of the Organ Procurement Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS) to be Centers for Medicare and Medicaid (CMS) certified and receive reimbursement. The three facilities approved to provide pancreas transplant services within Michigan are UNOS, OPTN, and CMS certified.
- Upon review, geographical access has not been identified by the Department or public as an indicative concern for patients seeking treatment services within Michigan. Currently, there are 19 patients awaiting a pancreas transplant, per the UNOS website.

⁴ <https://www.cms.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf>

⁵ <http://www.unos.org/about/index.php?topic=bylaws>

