Medical Coverage Policy | Uterus Transplantation for Absolute Uterine Factor Infertility

EFFECTIVE DATE: 10|01|2022
POLICY LAST UPDATED: 12|29|2022

OVERVIEW
Absolute uterine factor infertility is a condition in which an individual is unable to achieve pregnancy due to an absent or non-functioning uterus. Uterus transplantation may present a childbearing option that is an alternative to existing family planning pathways, including adoption, foster parenting, and gestational carrier pregnancy. Uterus transplantation is a complex, multi-stage process involving a living or deceased donor, recipient, and genetic partner.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Uterus transplantation for absolute uterine factor infertility is not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
Uterus transplantation for absolute uterine factor infertility is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

MEDICAL CRITERIA
Not applicable

BACKGROUND
Absolute Uterine Factor Infertility
Absolute uterine factor infertility (AUFI) refers to infertility that is attributable to an absent or non-functional uterus due to congenital, surgical, anatomical, or acquired factors that prevent embryo implantation and term pregnancy. AUFI is estimated to impact 1 in 500 females of childbearing age. Uterine agenesis or Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome results in the congenital absence of the uterus or presence of a rudimentary solid bipartite uterus. MRKH syndrome accounts for less than 3% of all müllerian malformations with an estimated prevalence of 1 in 4500 females. Individuals with MRKH syndrome type I present with 2 kidneys and are considered ideal candidates for uterine transplantation. Individuals with MRKH syndrome type II presenting with a single kidney have a higher risk of medication-induced nephrotoxicity and associated obstetric complications (eg, severe preeclampsia). Hysterectomy is the most common cause of acquired AUFI, with 240,000 procedures taking place in females under age 44 in the United States. In one clinical trial screening study of 239 individuals at the Cleveland Clinic, indications for uterus transplantation included prior hysterectomy (64%) and congenital anomalies (32%). Among individuals with prior hysterectomy, 50% were performed for benign indications, 25% for malignancy, and 25% for obstetric complications.

Uterus Transplantation

Uterus transplantation may provide a unique fertility restoration option for individuals desiring to carry and birth a child. Uterus transplantation is a complex, multi-stage process involving a living or deceased donor, recipient, and genetic partner. Once screening and consent is established for all involved parties, in-vitro fertilization is performed prior to transplantation to ensure fertilization and normal embryo development. The transplantation surgery involves radical hysterectomy in the donor to ensure long vascular pedicles for transplantation; however, several cases of robot assisted laparoscopic approaches have been reported. An advantage of uterus procurement in a deceased donor involves freedom to transect ureters, but this convenience is balanced by the potential for prolonged uterus ischemic time. The surgical approach in the recipient is dictated by underlying pelvic anatomy which may be impacted by AUFI etiology. For example, in individuals with Asherman syndrome, a traditional total hysterectomy must first be performed in the recipient. Immunosuppression is initiated at the time of transplantation and protocol and for-cause cervical biopsies enable monitoring for organ rejection. After 6 to 12 months of immunosuppression, embryo transfer, pregnancy, and cesarean delivery may follow. When childbearing has been deemed complete, the transplanted uterus is removed to avoid lifelong immunosuppression. Thus, uterus transplantation is the first form of organ transplantation intended to be temporary.

The first human uterus transplant was performed in 2000 in Saudi Arabia with a 46 year old living donor and 26 year old recipient with acquired AUFI due to hysterectomy for prior post-partum hemorrhage. Due to the development of acute vascular thrombosis at 3 months post-transplant, graft hysterectomy was required. The first successful live birth occurred in 2014 in Sweden in a 35 year old recipient with MRKH syndrome via a living, 61 year old, two-parous donor. The recipient was admitted with preeclampsia at 31 weeks, and a healthy male child was born 5 days later via cesarean delivery. The first live birth in the United States occurred in 2017 in a 29 year old recipient with MRKH syndrome via a living, 32 year old, two-parous donor. According to the Organ Procurement and Transplantation Network (OPTN), 35 uterus transplants have been performed in the United States via 13 deceased and 22 living donors as of March 2022.

Literature has explored the implications of uterus transplantation in transgender women, identifying several theoretical medical issues in genetic males meriting further investigation. These include creation of adequate de novo uterine vascularization, administration of appropriate hormone replacement therapy, and placement of the donor uterus in a nongynecoid pelvis.

For individuals with absolute uterine factor infertility (AUFI) who receive uterus transplantation, the evidence includes a systematic review and case series. Relevant outcomes are health status measures, perinatal outcomes, quality of life, treatment-related morbidity, and treatment-related mortality. One systematic review of 62 uterus transplants has reported 24 published live birth accounts, with an estimated overall live birth success rate exceeding 80% among surgically successful transplants. Surgical success rates have ranged from 64% to 78% for deceased and living donor procedures, respectively. Complications have been reported in 19% of recipients and 18% of living donors. High rates of preterm birth (80%) and episodes of acute respiratory distress syndrome in the newborn have been reported. Data for individuals with acquired AUFI are lacking. Further study is necessary to increase success rates, decrease complications and preterm births, and assess long-term outcomes in recipients and their children. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage

CODING

The following codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

0664T Donor hysterectomy (including cold preservation); open, from cadaver donor
0665T Donor hysterectomy (including cold preservation); open, from living donor
0666T Donor hysterectomy (including cold preservation); laparoscopic or robotic, from living donor

0667T Recipient uterus allograft transplantation from cadaver or living donor
0668T Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary
0669T Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each
0670T Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; arterial anastomosis, each

RELATED POLICIES
Not applicable

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