Medicare Advantage Policy Manual **Policy ID:** M-TRA19

Uterus Transplant

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

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.

MEDICARE ADVANTAGE POLICY CRITERIA

The Centers for Medicare & Medicaid Services (CMS) do not have an approved transplant program for uterine transplantation. Medically reasonable and necessary infertility treatment is covered under Medicare (*Medicare Benefit Policy Manual, Ch. 15, §20.1 – Physician Expense for Surgery, Childbirth, and Treatment for Infertility*); However, procedures must still have established evidence of safety and efficacy. Procedures which lack scientific evidence of safety and efficacy are investigational (experimental) and noncovered as they are considered not reasonable and necessary to treat illness or injury under Medicare *(Medicare Claims Processing Manual, Ch. 23, §30 A)*. Uterine transplantation does not have proven safety and efficacy and therefore is not medically reasonable or necessary under the Social Security Act Sec.1862 (a)(1)(A).

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	None
Medical Policy Manual	*Medicare coverage guidance is not available for uterus transplantation. Therefore, the health plan's medical policy is applicable.* Uterus Transplant, Transplant, Policy No. 19 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines the safety and efficacy of a device or drug but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and other Health Services, § 20.1 - Physician Expense for Surgery, Childbirth, and Treatment for Infertility
2. *Medicare Claims Processing Manual, Ch. 23, § 30. A*

CODING

Codes	Number	Description
CPT	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	Donor hysterectomy (including cold preservation); 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
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*