



MEDICAID MEDICAL POLICY
NORTH DAKOTA DEPARTMENT OF HUMAN SERVICES
MEDICAL SERVICES DIVISION
SFN 85 (6-9-2010)

Medicaid Policy Number (This number will be generated by Medical Services.) NDMP-2010-0001	Date Policy was Last Reviewed N/A
Title Hysteroscopic Tubal Occlusion (Essure® Sterilization)	
Effective Date 10/1/2010	
Revision Date(s) N/A	
Replaces N/A	
Cross References N/A	
Description Hysteroscopic tubal occlusion is designed for those women who desire permanent birth control. The device utilized is called Essure®. This device consists of a micro-insert made of metals (nickel titanium) and polyester fibers. The inserts are placed without incisions via the cervix to the fallopian tubes (bilaterally) using a hysteroscope and a small catheter to deliver the micro-inserts. Once in place, body tissue grows into the inserts, permanently blocking the fallopian tube. Three months (twelve weeks) after the procedure, women must undergo a hysterosalpingogram (x-ray of the uterus and fallopian tubes after an injection of an opaque material). This is done to confirm the micro-inserts are properly placed and tubal occlusion has taken place. Until that time, alternate birth control must be used. This form of birth control is considered to be irreversible.	
Scope Medical policies are systematically developed guidelines that serve as a resource for ND Medicaid staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the ND Medicaid program.	
Policy The Essure® sterilization procedure may be considered medically appropriate and necessary to women who have risk factors that prevent a physician from performing a safe and effective laparoscopic tubal ligation: (any of the following six criteria) <ul style="list-style-type: none">• Morbid obesity (BMI of 45 or greater)• Abdominal mesh that mechanically interferes with laparoscopic sterilization procedure• Permanent colostomy• Multiple abdominal/pelvic surgeries with documented severe adhesions• Artificial heart valve requiring continuous anticoagulation• Any severe medical problems that would contraindicate laparoscopy because of anesthesia consideration. The physician documentation must attest to the fact that general anesthesia would pose a substantial threat to the beneficiaries' life. Prior authorization is required (submit on MEDICAL PROCEDURE/DEVICE PRIOR AUTHORIZATION REQUEST form - SFN511) ONLY when the physician (MD/DO) recommends Hysteroscopic Tubal Occlusion be performed outside the stated ND Medical Services Medical Policy guidelines.	
Policy Guidelines This is a sterilization procedure, therefore all ND Medicaid sterilization policies apply. Please refer to the	

General Information for Providers Manual under the section entitled Sterilization.

Circumstances when hysteroscopic placement of bilateral Essure® micro-inserts should not be performed:

- Recipient is uncertain about her desire to end fertility
- Recipients in whom only one micro-insert can be placed (including recipients with apparent contralateral proximal tubal occlusion and patient with a suspected unicornuate uterus)
- Recipients who have previously undergone a tubal ligation

Or any recipient with any of the following conditions:

- Pregnancy or suspected pregnancy
- Delivery or termination of a pregnancy less than six weeks before Essure® micro-insert placement
- Active or recent upper or lower pelvic infection
- Known allergy to contrast media
- Known hypersensitivity to nickel confirmed by skin test

Benefit Application

- Coverage is limited to reimbursement for hysteroscopic placement of bilateral micro-inserts (CPT code 58565) including one set of Essure® micro-inserts per recipient, any provider, once in a lifetime.
- Reimbursement is made to licensed physicians/surgeons (MD/DO) only.
- Prior to attempting placement of the Essure® micro-inserts, the licensed physician must perform a thorough (diagnostic) hysteroscopic evaluation of the uterine cavity. The physician must be able to visualize both tubal ostia prior to attempting placement of the Essure micro-inserts (this is included in the reimbursement for CPT code 58565 and NOT separately billable).
- If the physician is unable to visualize both tubal ostia during the diagnostic hysteroscopic evaluation, the procedure should be terminated and the physician should bill for hysteroscopy, diagnostic (separate procedure) using CPT code 58555.

Rationale Source

References:

Summary of Risks and Other Important Information – The Essure System - CC-0366 13Nov08F
<http://essuremd.com/Portals/essuremd/PDFs/PST/CC-0366-01-13Nov08F.PDF> Accessed March 3, 2010

Matthew R. Hopkins, MD, et al. Retrospective cost analysis comparing Essure® hysteroscopic sterilization and laparoscopic bilateral tubal ligation. *Journal of Minimally Invasive Gynecology* (2007) 14, 97-102

Mark D. Levie, MD, et al. Office hysteroscopic sterilization compared with laparoscopic sterilization: A critical cost analysis. *Journal of Minimally Invasive Gynecology* (2005) 12, 318-322

Sophia N. Palmer, MD, et al. Transcervical sterilization: a comparison of Essure® permanent birth control system and Adiana® permanent contraception system. *Reviews in Obstetrics & Gynecology* (2009) Vol. 2 No. 2

D. F. Kraemer, et al. An economic comparison of female sterilization of hysteroscopic tubal occlusion with laparoscopic bilateral tubal ligation. *Contraception* 80 (2009) 254-260.

Code of Federal Regulations Citation(s)

42 CFR-Subpart F - 42 CFR 441.253; 42 CFR 441.254; 42 CFR 441.256; 42 CFR 441.257; 42 CFR 441.258

CODES	NUMBER	DESCRIPTION
CPT®	58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
	74740	Hysterosalpingography, radiological supervision and interpretation

	58340 74740	Catheterization and introduction of contrast material for hysterosalingography (at twelve weeks after placement of Essure®) Follow-up hysterosalingography to confirm bilateral tubal occlusion (at twelve weeks after placement of Essure®)
Applicable Modifier(s)	N/A	N/A
ICD-9 Procedures(s)	N/A	N/A
ICD-9 Diagnosis(es)	V25.2 V67.09 V26.51	Sterilization – admission for interruption of fallopian tubes or vas deferens Follow-up examination following other surgery (at twelve weeks after placement of Essure®) Tubal ligation status (at twelve weeks after placement of Essure®)
Applicable Revenue Codes(s)	N/A	N/A
HCPCS Code(s)	A4264	Permanent implantable contraceptive intratubal occlusion device(s) and delivery system. Currently ND Medicaid will include reimbursement for A4264-Essure® micro-insert(s) in the allowed amount for the procedure (58565). NO additional payment will be allowed for A4264.
Type of Service	Surgery	
Place of Service	Office	Place of Service Code 11

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The North Dakota Medicaid program adopts policies after careful review of published peer-review scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, North Dakota Medicaid reserves the right to review and update policies as appropriate. Always consult the General Information for Providers manual or North Dakota Medicaid Policy to determine coverage. CPT codes, descriptions and material are copyrighted by the American Medical Association.