

SUBJECT: TRANSRECTAL ULTRASOUND (TRUS)

POLICY NUMBER: 6.01.06

CATEGORY: Technology Assessment

EFFECTIVE DATE: 11/19/99

REVISED DATE: 03/21/02, 01/16/03, 12/18/03, 04/15/04, 06/16/05, 05/18/06, 03/15/07, 02/21/08

ARCHIVED DATE: 03/19/09

EDITED DATE: 03/18/10, 03/17/11, 03/15/12, 03/21/13, 03/20/14

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- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, transrectal ultrasound has medically proven to be effective and therefore, is **medically appropriate** for the following indications:
 - A. To guide biopsy of the *prostate* for patients with palpable prostatic nodules or an increase in the prostate-specific antigen (PSA) without a palpable prostatic nodule.
 - B. For the following *prostate* indications:
 1. guiding the placement of radioactive seed implantation and determining the volume of prostate prior to brachytherapy treatment for prostate cancer;
 2. guiding the placement of cryoprobes, monitoring the freezing process in real time during a prostatic cryosurgical ablation procedure and determining the volume of the prostate prior to the cryosurgical surgery;
 3. to evaluate hematospermia, azoospermia and prostatic/ejaculatory duct cysts and/or obstruction for infertility;
 4. to evaluate possible prostatic abscesses which can be drained through TRUS guidance; or
 5. to assess prostate volume when size of gland influences treatment selection.
 - C. For the following *colorectal* indications:
 1. staging of rectal carcinoma;
 2. evaluation of complex rectal masses, fistulae, or abscesses;
 3. evaluation of fecal incontinence; or
 4. suspected rectovaginal endometriosis.
- II. Based upon our criteria and assessment of peer-reviewed literature, transrectal ultrasound has not been medically proven to be effective for the following applications and therefore is considered **investigational**:
 - A. as the sole means of diagnosing prostate cancer,
 - B. staging of prostate cancer,
 - C. screening for prostate cancer, or
 - D. monitoring the response of prostate cancer to treatment, or
 - E. monitoring the response of rectal cancer to treatment.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

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DESCRIPTION:

Transrectal ultrasound (TRUS) is a diagnostic imaging procedure used in the diagnosis, staging and management of malignant diseases of the prostate, rectum and surrounding tissues. It is also intended to guide biopsy of the prostate, implantation of radioactive material, or cryoprobes for treatment of prostate cancer. TRUS may also be used in the work-up of patients with hematospermia or in patients with benign prostatic hypertrophy (BPH) where prostate volume may influence the selection of a treatment procedure. It is also used to evaluate rectovaginal endometriosis. Instrumentation consists of a transducer (probe) which is inserted into the rectum, a radial and/or linear scanner and an imaging screen.

RATIONALE:

TRUS, when used as primary diagnostic tool, is limited, as there is considerable difficulty in distinguishing malignant from benign tumors. TRUS's sensitivity and specificity in detection of prostate cancer is poor in comparison to other measures such as PSA assay. There is no direct evidence that TRUS, as a screening tool, improves disease-specific survival rates.

Studies have shown that the overall accuracy of TRUS is only 50% for staging of prostate cancers. TRUS has been found to over and under-stage prostate cancers.

The available evidence does not support the conclusion that TRUS improves health outcomes when used to monitor the course of a patient's disease or after initiation of treatment for prostate cancer.

There are minimal data on the use of TRUS to monitor patients for recurrence of rectal cancer after treatment. Treatment related disruption of the normal anatomy, inflammation, and fibrosis, limit the ability of TRUS to distinguish between mucosal layers.

Studies have shown that TRUS is a useful tool in evaluating the extension of endometriosis to the rectal tissue.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	76872 Ultrasound, transrectal 76873 Prostate volume study for brachytherapy treatment planning (separate procedure) 76942 Ultrasonic guidance for needle placement (e.g. biopsy, aspiration, injection, localization device), imaging supervision and interpretation
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HCPCS: No code(s)

<u>ICD9:</u>	154.0 - 154.8 Malignant neoplasm of rectum, rectosigmoid junction and anus 185 Malignant neoplasm of prostate 197.5 Secondary malignant neoplasm of respiratory and digestive systems, large intestine and rectum
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198.82	Secondary malignant neoplasm of other specified sites, genital organs
211.4	Benign neoplasm of rectum and anal canal
222.2	Benign neoplasm of male genital organs, prostate
230.4 - .6	Carcinoma in situ of rectum, anus
233.4	Carcinoma in situ of breast and genitourinary system, prostate
235.2	Neoplasm of uncertain behavior, rectum
236.5	Neoplasm of uncertain behavior of genitourinary organs, prostate
565.1	Anal fistula
566	Abscess of anal and rectal regions
569.49	Other specified disorders of rectum and anus, other
600.00-600.01	Hypertrophy (benign) of prostate, without or with urinary obstruction
600.10-600.11	Nodular prostate, without or with urinary obstruction
601.2	Abscess of prostate
606.0 - .9	Azoospermia and unspecified male infertility
617.4	Endometriosis rectovaginal septum
617.5	Endometriosis rectum
619.1	Digestive-genital tract fistula, female
624.4	Old laceration or scarring of vulva
624.9	Unspecified noninflammatory disorder of vulva and perineum
787.60-787.63	Incontinence of feces (code range)
790.93	Elevated prostate specific antigen (PSA)
V10.06	Personal history of malignant neoplasm, rectum, rectosigmoid junction, and anus
V10.46	Personal history of malignant neoplasm, prostate
V71.1 (E/I)	Observation of suspected malignant neoplasm
ICD10:	
C19-C21.8	Malignant neoplasm of rectum, anus and anal canal (code range)
C61	Malignant neoplasm of prostate
C78.5	Secondary malignant neoplasm of large intestine and rectum
C79.82	Secondary malignant neoplasm of genital organs
D01.1-D01.3	Carcinoma in situ of rectum, anus and anal canal (code range)
D07.5	Carcinoma in situ of prostate
D12.7-D12.9	Benign neoplasm of rectum, anus and anal canal (code range)
D29.1	Benign neoplasm of prostate

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D37.1-D37.5	Neoplasm of uncertain behavior of digestive organs (code range)
D40.0	Neoplasm of uncertain behavior of prostate
K50.114-K50.914	Crohn's disease (code range)
K60.3-K60.5	Fissure and fistula of anal and rectal regions (code range)
K61.0-K61.4	Abscess of anal and rectal regions (code range)
K62.7	Radiation proctitis
K62.89	Other specified diseases of anus and rectum
K62.9	Disease of anus and rectum, unspecified
N40.0-N40.3	Enlarged prostate with or without lower urinary tract symptoms (code range)
N41.2	Abscess of prostate
N46.01-N46.9	Male infertility (code range)
N80.4-N80.5	Endometriosis (code range)
N82.2-N82.4	Fistulae involving female genital tract (code range)
N90.89-N90.9	Other specified or unspecified noninflammatory disorders of vulva and perineum (code range)
R15.0-R15.9	Fecal incontinence (code range)
R97.2	Elevated prostate specific antigen (PSA)
Z03.89	Encounter for observation for other suspected diseases and conditions ruled out
Z85.048	Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus
Z85.46	Personal history of malignant neoplasm of prostate

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KEY WORDS:

Transrectal echography.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Transrectal Ultrasound. Please refer to the following LCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=26876&ContrId=181&ver=52&ContrVer=1&CntrctrSelected=181*1&Cntrctr=181&name=National+Government+Services%2c+Inc.+%2813202%2c+MAC+-+Part+B%29&s=41&DocType=All&bc=AggAAAAIAAAAAAA%3d%3d&