MEDICAL POLICY

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

• 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.
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:

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>76872</td>
<td>Ultrasound, transrectal</td>
</tr>
<tr>
<td>76873</td>
<td>Prostate volume study for brachytherapy treatment planning (separate procedure)</td>
</tr>
<tr>
<td>76942</td>
<td>Ultrasonic guidance for needle placement (e.g. biopsy, aspiration, injection, localization device), imaging supervision and interpretation</td>
</tr>
</tbody>
</table>

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

HCPCS: No code(s)

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

REFERENCES:


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**KEY WORDS:**

Transrectal echography.

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**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&CntrsSelected=181*1&Cntrcr=181&name=National+Government+Services%2c+Inc.+%2813202%2c+MAC+-+Part+B%29&s=41&DocType=All&bc=AggAAAAA%3d%3d&](http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=26876&ContrId=181&ver=52&ContrVer=1&CntrsSelected=181*1&Cntrcr=181&name=National+Government+Services%2c+Inc.+%2813202%2c+MAC+-+Part+B%29&s=41&DocType=All&bc=AggAAAAA%3d%3d&).