



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date 6/15/2011
Next Review Date 6/15/2012
Coverage Policy Number 0344

Subject Transrectal Ultrasound (TRUS)

Table of Contents

Coverage Policy	1
General Background	2
Coding/Billing Information	6
References	7
Policy History	12

Hyperlink to Related Coverage Policies

- Brachytherapy for Prostate Cancer
- Cryoablation for Prostate Cancer
- Infertility Services
- Intensity-Modulated Radiation Therapy (IMRT)
- Prostate Saturation Biopsy
- Prostate-Specific Antigen (PSA) Screening for Prostate Cancer

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA covers transrectal ultrasound (TRUS) as medically necessary for ANY of the following indications:

- evaluation of an abnormal digital rectal exam (DRE) and/or abnormal prostate specific antigen (PSA)
- measurement of prostate volume for treatment planning and/or monitoring
- guidance during biopsy of the prostate or rectum
- staging of clinically localized prostate cancer
- guidance during the delivery of prostate cancer treatment (e.g., brachytherapy)
- monitoring prostate cryotherapy
- evaluation and aspiration of prostate abscess
- monitoring the response to prostate or rectal cancer treatment
- staging of rectal carcinoma
- suspected congenital anomaly of the prostate, rectum, seminal vesicle or surrounding tissue
- diagnosis and/or monitoring of an azoospermic or oligospermic individual with palpable vasa and low ejaculate volume, subject to the terms, conditions and limitations of the Infertility Services benefit and other plan provisions detailed in the applicable benefit plan document
- evaluation of lower urinary tract symptoms (e.g., pelvic pain, prostatitis/prostodynia, obstructive and irritative voiding symptoms)

CIGNA does not cover TRUS for any other indication, including but not limited to the following, because it is considered experimental, investigational or unproven:

- use as a stand-alone screening tool for prostate or rectal cancer
 - transrectal high-intensity focused ultrasound (HIFU) prostate cancer treatment
-

General Background

Transrectal Ultrasound (TRUS)

A TRUS or endorectal ultrasound is a procedure in which a probe that sends out high-energy sound waves is inserted into the rectum. The sound waves are bounced off internal tissues or organs and make echoes. The echoes form a picture of body tissue called a sonogram. TRUS is used to look for abnormalities in the rectum and nearby structures, including the prostate (National Cancer Institute [NCI], 2010).

Textbook literature and reviews cite many indications for TRUS. TRUS-guided, systematic needle biopsy is reported to be the most reliable method to ensure accurate sampling of prostatic tissue in those men considered at high risk for prostatic cancer based on digital rectal exam (DRE) and prostate specific antigen (PSA) findings. The sensitivity of TRUS-guided biopsies is reported to be 70–80%. TRUS provides good-quality images of the prostate gland because a high-frequency probe can be placed in the rectum close to the prostate. TRUS has been evaluated for preoperative staging and the detection of postoperative recurrence of rectal cancer. The depth of cancer invasion into the rectal wall and surrounding tissues and the presence of malignant perirectal lymph nodes have been evaluated using TRUS. TRUS is used for real-time monitoring of the freezing process during cryosurgery. TRUS can be used in diagnosing medial prostatic cysts in patients with prostatitis-like symptoms, diagnosing and draining prostatic abscesses or diagnosing and draining obstructed seminal vesicles. For benign prostatic hyperplasia (BPH), TRUS is reported to be more precise than cystoscopy in determining the exact size of the prostate when determining whether a patient should have an open prostatectomy. If the patient is not diagnosed with cancer, then prostate volume assessment by TRUS might assist in directing patient therapy for obstructive voiding symptoms. TRUS allows for the anatomic visualization of the prostate, seminal vesicles, and ampullary portion of the vas deferens. TRUS is indicated in azoospermic patients suspected of having ejaculatory duct obstruction. TRUS has provided an improved monitoring system compared with free-hand or fluoroscopically-guided radioactive source deposition in image guidance and brachytherapy. TRUS has been suggested as a screening tool for prostate cancer but is not routinely used due to its limited sensitivity and specificity (Zelevsky, et al., 2008; Akin, et al., 2007; Wein, et al., 2007; Manyak, 2006; Boczko, et al., 2006; Amiel, et al., 2006; Lee, et al., 2006; Wasserman, 2006; Kutikov, et al., 2006; Yamada, et al., 2003).

The primary modalities used to determine the extent of prostate and rectal cancers are DRE, serum PSA, computed tomographic scanning (CT), magnetic resonance imaging (MRI) and TRUS (Engstrom, et al., 2009; Schaffzin, et al., 2004). Research is ongoing on the clinical efficacy of combining modalities (Singh, et al., 2008).

Power doppler TRUS is the next generation of imaging. It is reported that power doppler has the advantage of increased sensitivity for detecting small, low-flow blood vessels. Therefore, the diagnosis of BPH can be improved by the assessment of intraprostatic vascularity. Power and color dopplers are currently available on transrectal probes. Power doppler imaging is reported to be 3–5 times more sensitive for assessment of blood flow than color doppler imaging (Amiel, et al., 2006).

Literature Review TRUS

Textbook literature, professional society guidelines and studies in the published, peer-reviewed medical literature have reported the diagnostic utility of TRUS for multiple indications (Leibovici, et al., 2005; Song, et al., 2005; Schaffzin, et al., 2004; Aarnink, et al., 1998; Smith, et al., 1997).

Transrectal High Intensity Focused Ultrasound (HIFU)

Methods to manage localized prostate cancer include watchful waiting and active surveillance. Treatment options for localized prostate cancer include radical prostatectomy, radiotherapy, brachytherapy, cryotherapy, and intensity-modulated radiation therapy. HIFU was first proposed as a treatment of BPH and now is being proposed as primary therapy for patients with localized, low-grade prostate cancer or as salvage therapy in patients with recurrence after radiotherapy. HIFU is a minimally invasive procedure using a transrectal

ultrasound probe to image the prostate and deliver timed bursts of heat to create coagulation necrosis in a targeted area without harming adjacent healthy tissue. A cooling balloon surrounding the probe protects the rectal mucosa from the high temperature. HIFU treatment can be repeated if necessary. This procedure is typically carried out in an outpatient setting and is performed under a spinal or general anesthesia. HIFU has also been used to treat small renal and testicular tumors. Prolonged urinary retention secondary to edema and urethral sloughing have been the most common reported complications following primary HIFU treatment. Therefore, many of the current HIFU techniques include a pre-procedural TURP. Reported long-term complications following salvage HIFU include rectourethral fistulas, incontinence, rectal or perineal pain, and bladder neck contractures or urethral strictures (ECRI, 2010; NICE, 2008; Rebillard, et al., 2008; Zelefsky, et al., 2008; Prostate Cancer Research Institute [PCRI], 2008; Catalona, et al., 2007; Uchida, et al., 2006a; National Institute for Clinical Excellence (NICE), 2005).

U.S. Food and Drug Administration (FDA)

The Sonablate[®] 500 is manufactured by Focus Surgery (Indianapolis, IN) and Misonix, Inc. (Farmingdale, NY) and is approved by the FDA as an investigational device for clinical trials in the U.S.. The Ablatherm[®] HIFU device is manufactured by EDAP TMS S.A.(Vaulx-en-Velin, France). At this time, neither device has received pre-market approval or 510(k) clearance.

Literature Review HIFU

The peer-reviewed published literature consists of non-randomized studies and uncontrolled case series studies. The long-term efficacy, safety and long-term health outcomes of HIFU prostate cancer treatment has not been established in controlled clinical trials. Overall, there is insufficient information to recommend HIFU as standard therapy (Crouzet, et al., 2010; Shoji, et al., 2010; ECRI, 2010; NICE, 2008; Wilt, et al., 2008; Catalona, et al., 2007; Blana, et al., 2007; Uchida, et al., 2005; Blana, et al., 2004).

Lukka et al. (2010) conducted a systematic review of the literature to evaluate the evidence comparing HIFU with standard treatment in patients with localized prostate cancer. No randomized controlled trials or meta-analyses were identified. Seven systematic reviews and two practice guidelines were identified; neither contained randomized controlled trials. Adjusting the selection criteria to include case series found 34 clinical studies of HIFU. Twenty-nine evaluated HIFU as the primary treatment and five examined HIFU as salvage treatment for recurrence after radiotherapy. In most studies the outcomes used to determine efficacy were negative biopsy rates or prostate-specific antigen (PSA) levels. The authors reported that the current evidence on HIFU use in prostate cancer patients is of low quality, rendering it difficult to draw conclusions about its efficacy. Until results from case series are confirmed in prospective studies, the widespread use of HIFU is not supported.

Rebillard et al. (2008) conducted a systematic review of the literature. The authors reported that published clinical studies on HIFU are limited to case series; neither randomized studies comparing HIFU with another technique or active surveillance, nor studies with matched controls were found. Most papers originated in a few centers and it appears that several articles related to the same study with different numbers of patients and/or different times of follow-up. Most reports were of single-center studies. The authors reported that long-term follow-up studies are needed to further evaluate cancer-specific and overall survival rates. In addition, the efficacy and safety of HIFU as a primary therapy should be further evaluated in randomized controlled trials comparing it with other (minimally invasive) therapies.

In an Agency for HealthCare Review and Quality (AHRQ) systematic review on comparative effectiveness and harms of treatments for clinically localized prostate cancer, HIFU is not discussed as a treatment option. The authors reported that assessment of the comparative effectiveness and harms of localized prostate cancer treatments is difficult because of limitations in the evidence (Wilt, et al, 2008).

The 2008 NICE guidance report on prostate cancer diagnosis and treatment, recommends that there is limited evidence of the clinical effectiveness of HIFU in comparison to established interventions to recommend routine use. HIFU is not recommended for locally advanced prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions.

In 2005 NICE issued a guidance report on HIFU for prostate cancer. The authors stated that the effect of HIFU for prostate cancer on quality of life and long-term survival remains uncertain. Additionally, interpretation of the data was difficult since it was not clear from the literature when the procedure was used for primary or salvage

treatment. The authors stated that the current evidence on the safety and efficacy of HIFU as measured by reduction in PSA levels and biopsy findings appears adequate to support the use of HIFU for the treatment of prostate cancer, provided the normal arrangements are in place for consent, audit and clinical governance.

Professional Societies/Organizations

American Urological Association (AUA): The AUA Best Practice Statements, Evaluation of the Azoospermic Male and Optimal Evaluation of the Infertile Male, are a part of an updated series on male infertility prepared by the Male Infertility Best Practice Statement Panel. The Evaluation of the Azoospermic Male recommendations state that, "Transrectal ultrasonography, with or without seminal vesicle aspiration and seminal vesiculography, may be used to identify obstruction in the distal male reproductive tract." The Optimal Evaluation of the Infertile Male recommendations state that, "Transrectal ultrasonography is indicated in azoospermic patients with palpable vasa and low ejaculate volumes to determine if ejaculatory duct obstruction exists. Some experts recommend transrectal ultrasonography for oligospermic patients with low volume ejaculates, palpable vasa and normal testicular size to determine if partial ejaculatory duct obstruction is present" (AUA, 2010).

The AUA Guideline for the Management of Clinically Localized Prostate Cancer reports that standard options for the management of clinically localized prostate cancer include watchful waiting and active surveillance, interstitial prostate brachytherapy, external beam radiotherapy, radical prostatectomy, as well as primary hormonal therapy. The authors report that prior to initiating brachytherapy, a TRUS-based volume study is performed to assess prostate volume and to determine the number of needles and corresponding radioactive seeds, the isotope, and the isotope strength necessary for the procedure. The radioactive needles are implanted via a transperineal approach under guidance of TRUS or MRI. HIFU is listed under other treatment options in this guideline. The panel did not include other treatment options in the analysis and recommendations due to a combination of factors, including limited published experience and short-term follow-up as well as the similar issues that affected evaluations of other treatment options (Thompson, et al., 2009).

Ultrasound is an integral part of standard urological practice. The American Urological Association, Inc[®] (AUA) developed a consensus statement on urologic ultrasound which describes indications for TRUS of the prostate (AUA, 2007). There has been no update to this consensus statement since 2007.

Indications for TRUS of the prostate include but are not limited to (not indicated for screening procedures):

- measurement of prostate volume
- investigation of abnormal DRE and abnormal PSA
- prostatic assessment with sonographic directed biopsy
- evaluation for and aspiration of prostate abscess
- assessment for suspected congenital abnormality
- evaluation of lower urinary tract symptoms (i.e., pelvic pain, prostatitis/prostodynia or obstruction and irritative voiding symptoms)
- evaluation of hematospermia
- evaluation of infertility (i.e., azoospermia or low ejaculate volume or impaired semen quality)
- monitor cryotherapy
- direct radioactive seed implantation
- evaluation for local recurrence post-treatment for prostate cancer
- placement of fiducial markers for image-guided radiation therapy
- doppler studies may be performed to identify the neurovascular bundles or demonstrate intraprostatic blood flow

The 2009 AUA prostate-specific antigen best practice statement reports that transrectal ultrasonography adds no additional information to the combination of PSA testing and DRE as screening tests, but is useful in biopsy guidance and staging. The authors report that that the presence of prostate cancer cannot be excluded on the basis of ultrasonography alone, there is no role for transrectal ultrasound by itself in screening for cancer (AUA, 2009).

American College of Radiology (ACR): The ACR Practice Guideline for the Performance of Ultrasound Evaluation of the Prostate (and Surrounding Structures) states that ultrasound examination of the prostate is used in the diagnosis of prostate cancer, BPH, prostatitis male infertility, and for the treatment of prostatic

cancer, abscess, and BPH. For prostate screening, a combination of DRE and PSA level usually serves as the initial screening procedure. The ACR states that ultrasound examination of the prostate is best reserved to evaluate those patients who have abnormal DREs or abnormal serum PSA levels. Ultrasound findings may strongly suggest the presence of prostate cancer, but ultrasound evaluation alone cannot confirm or exclude the diagnosis of prostate cancer. Ultrasound is useful for documenting the size of the gland in patients with prostatism. Ultrasound of the prostate and surrounding structures may also be useful in the evaluation of male infertility and in the setting of infection to assess the extent of the process and to determine whether there is an associated abscess. The transrectal approach to ultrasound of the prostate is preferred, as the quality of the imaging is superior to transabdominal or transperineal examinations. The ACR notes that Doppler sonography may be helpful in detecting areas of neovascularity that can be used to select sites for potential biopsy (ACR, 2010).

ACR Appropriateness Criteria®: The ACR issues Appropriateness Criteria on a variety of diagnoses and conditions. In these criteria, various imaging methods are rated on an appropriateness scale of 1–9, with one being the least appropriate imaging modality and nine being the most appropriate imaging modality for a given diagnosis or condition.

- In the ACR Appropriateness Criteria for obstructive voiding symptoms secondary to prostate disease, for normal renal function or increased blood urea nitrogen (BUN) and/or creatinine conditions, TRUS of the bladder is rated a two (ACR, 2010).
- In the ACR Appropriateness Criteria for pretreatment staging of clinically localized prostate cancer, TRUS is not rated. Regarding the role of TRUS in staging prostate cancer, the criteria state that if either the DRE or PSA test suggests neoplasm, a transrectal ultrasound-guided needle biopsy of the prostate gland is usually performed (ACR, 2009).
- In the ACR Appropriateness Criteria for pretreatment staging of colorectal cancer, TRUS of rectal cancer (small or superficial) is given a rating of eight. For rectal large rectal lesion TRUS is given a rating of six (ACR, 2008).

American Gastroenterological Association (AGA): The joint guideline from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the ACR on screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, does not mention TRUS (Levin, et al., 2008).

U.S. Preventive Services Task Force (USPSTF): The summary of the 2008 recommendation of the U.S. Preventive Services Task Force (USPSTF) on screening for prostate cancer does not reference TRUS as a screening method (USPSTF, 2008).

National Comprehensive Cancer Network® (NCCN®): The NCCN Clinical Practice Guidelines in Oncology™ Rectal Cancer states that, “endorectal ultrasound or endorectal or pelvic MRI, and CT scans of the chest, abdomen and pelvis are recommended for the preoperative staging of rectal cancer” (NCCN, 2011).

The NCCN Clinical Practice Guidelines in Oncology Prostate Cancer states that “definitive diagnosis requires biopsies of the prostate usually performed by the urologist using a needle under transrectal ultrasound guidance” (NCCN, 2011). This guideline does not include HIFU among the therapeutic options for localized prostate cancer.

The NCCN Clinical Practice Guidelines in Oncology Prostate Cancer Early Detection states that PSA density requires measurement of prostate volume by TRUS. In addition, this NCCN guideline notes that the diagnosis of prostate cancer requires a biopsy of the prostate, usually performed by a needle, under TRUS guidance (NCCN, 2010).

Summary

Transrectal Ultrasound (TRUS) involves no exposure to ionizing radiation and is well tolerated by patients. Evidence in the published peer-reviewed medical literature as well as professional society guidelines support the diagnostic utility of TRUS in a variety of clinical situations, including, but not limited to, investigation of abnormal digital rectal exam (DRE) and abnormal prostate specific antigen (PSA), measurement of prostate volume, guidance during biopsy of the prostate or rectum, staging of clinically localized prostate cancer, staging

rectal carcinoma, delivery of prostate cancer treatment (e.g., brachytherapy), monitoring cyrotherapy, evaluation of lower urinary tract symptoms, monitoring the response to prostate or rectal cancer treatment, and male infertility. The clinical efficacy of TRUS as a stand-alone screening tool for prostate or rectal cancer has not been proven in controlled clinical studies.

The long-term efficacy and safety of transrectal high-intensity focused ultrasound (HIFU) prostate cancer treatment compared to established interventions (e.g., prostatectomy and radiotherapy) has not been proven in controlled clinical trials. Presently, there are no U.S. Food and Drug Administration (FDA)-approved HIFU devices.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
76872	Ultrasound, transrectal
76873	Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning (separate procedure)

ICD-9-CM Diagnosis Codes	Description
154.0–154.8	Malignant neoplasm of rectum, rectosigmoid junction, and anus
185	Malignant neoplasm of prostate
197.5	Secondary malignant neoplasm of large intestine and rectum
198.82	Secondary malignant neoplasm of genital organs
211.4	Benign neoplasm of rectum and anal canal
222.2	Benign neoplasm of male genital organs, prostate
230.4	Carcinoma in situ, rectum
233.4	Carcinoma in situ, prostate
235.2	Neoplasm of uncertain behavior, stomach, intestines, and rectum
236.5	Neoplasm of uncertain behavior of genitourinary organs, prostate
239.5	
599.60– 599.69	Urinary obstruction
599.7-599.72	Hematuria
600.0-600.91	Hyperplasia of prostate
601.0–601.9	Inflammatory diseases of prostate
602.9	Unspecified disorder of prostate
606.0	Azoospermia
606.1	Oligospermia
608.82	Hemospermia
787.6	Incontinence of feces
788.1	Dysuria
788.20	Retention of urine, unspecified
788.21	Incomplete bladder emptying
790.93	Other nonspecific findings on examination of blood, elevated prostate specific antigen (PSA)
V10.06	Personal history of malignant neoplasm of rectum, rectosigmoid junction, and anus

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
V76.41	Screening for malignant neoplasm of the rectum
V76.44	Special screening for malignant neoplasm of prostate

Experimental/Investigational/Unproven/Not Covered when used to report transrectal high-intensity focused ultrasound (HIFU) prostate cancer treatment:

CPT ^{®*} Codes	Description
55899	Unlisted procedure, male genital system
76999	Unlisted ultrasound procedure (eg, diagnostic, interventional)

ICD-9-CM Diagnosis Codes	Description
185	Malignant neoplasm of prostate
198.82	Secondary malignant neoplasm of genital organs
233.4	Carcinoma in situ, prostate

***Current Procedural Terminology (CPT[®]) © 2010 American Medical Association: Chicago, IL.**

References

1. Aarnink RG, Beerlage HP, De La Rosette JJ, Debruyne FM, Wijkstra H. Transrectal ultrasound of the prostate: innovations and future applications. J Urol. 1998 May;159(5):1568-79.
2. Akin O, Hricak H. Imaging of prostate cancer. Radiol Clin North Am. 2007 Jan;45(1):207-22.
3. American College of Radiology (ACR). ACR practice guideline for the performance of ultrasound evaluation of the prostate (and surrounding structures). Originally published 1992. Revised 1996, 2000, 2005, 2010 (effective 2010 Oct 1). Accessed April 19, 2011. Available at URL address: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/us.aspx
4. American College of Radiology (ACR). ACR Appropriateness Criteria[®]. Pretreatment staging prostate cancer. Date of origin 2005. Last review date 2009. Accessed April 19, 2011. Available at URL address: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx
5. American College of Radiology (ACR). ACR Appropriateness Criteria[®]. Obstructive voiding symptoms secondary to prostate disease. Date of origin 1995. Last review date 2010. Accessed April 19, 2011. Available at URL address: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx
6. American College of Radiology (ACR). ACR Appropriateness Criteria[®]. Pretreatment staging or colorectal cancer. Date of origin 1996. Last review date 2008. Accessed April 19, 2011. Available at URL address: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria.aspx
7. American Urological Association (AUA). The evaluation of the azoospermic male: AUA best practice statement. Revised, 2010. Accessed April 19, 2011. Available at URL address: <http://www.auanet.org/content/about-us/about-us.cfm>
8. American Urological Association (AUA). Optimal evaluation of the infertile male: AUA best practice statement. Revised, 2010. Accessed April 19, 2011. Available at URL address: <http://www.auanet.org/content/about-us/about-us.cfm>

9. American Urological Association (AUA). Prostate specific antigen: best practice statement. 2009 update. Accessed April 19, 2011. Available at URL address: <http://www.auanet.org/content/about-us/about-us.cfm>
10. American Urological Association (AUA). Consensus Statement on Urologic Ultrasound Utilization. Feb 2007 revised. Accessed April 19, 2011. Available at URL address: <http://www.auanet.org/content/about-us/about-us.cfm>
11. Amiel GE, Slawin KM. Newer modalities of ultrasound imaging and treatment of the prostate. *Urol Clin North Am.* 2006 Aug;33(3):329-37.
12. Aus G. Current status of HIFU and cryotherapy in prostate cancer--a review. *Eur Urol.* 2006 Nov;50(5):927-34.
13. Blana A, Murat FJ, Walter B, Thuroff S, Wieland WF, Chaussy C, et al. First Analysis of the Long-Term Results with Transrectal HIFU in Patients with Localised Prostate Cancer. *Eur Urol.* 2007 Nov 5 [Epub ahead of print].
14. Blana A, Walter B, Rogenhofer S, Wieland WF. High-intensity focused ultrasound for the treatment of localized prostate cancer: 5-year experience. *Urology.* 2004 Feb;63(2):297-300.
15. Boczeko J, Messing E, Dogra V. Transrectal sonography in prostate evaluation. *Radiol Clin North Am.* 2006 Sep;44(5):679-87.
16. Bradford TJ, Montie JE, Hafez KS. The role of imaging in the surveillance of urologic malignancies. *Urol Clin North Am.* 2006 Aug;33(3):377-96.
17. Catalona WJ, Han M. Definitive therapy for localized prostate cancer-an overview. *Wein: Campbell-Walsh Urology.* 9th ed., Philadelphia, PA: Saunders; 2007. Ch. 95.
18. ClinicalTrials.gov. Accessed April 19, 2011. Available at URL address: <http://clinicaltrials.gov/ct2/results?term=high-intensity+focused+ultrasound>
19. Crouzet S, Rebillard X, Chevallier D, Rischmann P, Pasticier G, Garcia G, et al. Multicentric oncologic outcomes of high-intensity focused ultrasound for localized prostate cancer in 803 patients. *Eur Urol.* 2010 Oct;58(4):559-66. Epub 2010 Jul 3.
20. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute;2010 Oct 1. High-intensity Focused Ultrasound for Benign Prostatic Hyperplasia and Prostate Cancer. Available at URL address: <http://www.ecri.org>
21. Focus Surgery, Inc. 2007. Accessed April 19, 2011. Available at URL address: <http://www.focus-surgery.com/>
22. Gollub MJ, Schwartz LH, Akhurst T. Update on colorectal cancer imaging. *Radiol Clin North Am.* 2007 Jan;45(1):85-118.
23. Gosselaar C, Roobol MJ, Roemeling S, de Vries SH, Cruijsen-Koeter I, van der Kwast TH, et al.; European Randomized Study of Screening for Prostate Cancer (ERSPC). Screening for prostate cancer without digital rectal examination and transrectal ultrasound: results after four years in the European Randomized Study of Screening for Prostate Cancer (ERSPC), Rotterdam. *Prostate.* 2006 May 1;66(6):625-31.
24. Katz S and Rosen M. MR imaging and MR spectroscopy in prostate cancer management. *Radiol Clin North Am.* 2006 Sep;44(5):723-34.

25. Koch MO, Gardner T, Cheng L, Fedewa RJ, Seip R, Sanghvi NT. Phase I/II trial of high intensity focused ultrasound for the treatment of previously untreated localized prostate cancer. *J Urol*. 2007 Dec;178(6):2366-70; discussion 2370-1.
26. Kutikov A, Guzzo TJ, Malkowicz SB. Clinical approach to the prostate: an update. *Radiol Clin North Am*. 2006 Sep;44(5):649-63.
27. Lee AK, Frank SJ. Update on radiation therapy in prostate cancer. *Hematol Oncol Clin North Am*. 2006 Aug;20(4):857-78.
28. Leibovici D, Kamat AM, Do KA, Pettaway CA, Ng CS, Evans RB, et al. Transrectal ultrasound versus magnetic resonance imaging for detection of rectal wall invasion by prostate cancer. *Prostate*. 2005 Jan 1;62(1):101-4.
29. Levin B, Lieberman DA, McFarland B, Andrews KS, Brooks D, Dash C, et al; American Cancer Society Colorectal Cancer Advisory Group, the US Multi-Society Task Force, and the American College of Radiology Colon Cancer Committee. Screening and Surveillance for the Early Detection of Colorectal Cancer and Adenomatous Polyps, 2008: A Joint Guideline From the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. *Gastroenterology*. 2008 Feb 8 [Epub ahead of print].
30. Lukka H, Waldron T, Chin J, Mayhew L, Warde P, Winkquist E, et al. High-intensity focused ultrasound for prostate cancer: a practice guideline. *Can Urol Assoc J*. 2010 Aug;4(4):232-6.
31. Lukka H, Waldron T, Chin J, Mayhew L, Warde P, Winkquist E, et al.; Genitourinary Cancer Disease Site Group of Cancer Care Ontario's Program in Evidence-Based Care. High-intensity focused ultrasound for prostate cancer: a systematic review. *Clin Oncol (R Coll Radiol)*. 2011 Mar;23(2):117-27. Epub 2010 Oct 6.
32. Manyak MJ, Javitt M, Kang PS, Kreuger WR, Storm ES. The evolution of imaging in advanced prostate cancer. *Urol Clin North Am*. 2006 May;33(2):133-46.
33. Morey SS. AUA issues a policy report on PSA monitoring. The American Urological Association. *Am Fam Physician*. 2000 Aug 15;62(4):883-4.
34. Muto S, Yoshii T, Saito K, Kamiyama Y, Ide H, Horie S. Focal therapy with high-intensity-focused ultrasound in the treatment of localized prostate cancer. *Jpn J Clin Oncol*. 2008 Mar;38(3):192-9.
35. National Cancer Institute. Prostate Cancer (PDQ[®]): Treatment. Patient Version. Modified Nov 5, 2010. Accessed April 19, 2011. Available at URL address: <http://www.cancer.gov/cancertopics/pdq/treatment/prostate/Patient>
36. National Cancer Institute. Dictionary of cancer terms. Transrectal ultrasound. Accessed April 19, 2011. Available at URL address: <http://www.cancer.gov/dictionary>
37. National Comprehensive Cancer Network[®] (NCCN). NCCN GUIDELINES[™] Clinical Guidelines in Oncology[™]. © National Comprehensive Cancer Network, Inc 2011, All Rights Reserved. Rectal cancer. 4.2011. Accessed April 20, 2011. Available at URL address: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
38. National Comprehensive Cancer Network[®] (NCCN). NCCN GUIDELINES[™] Clinical Guidelines in Oncology[™]. © National Comprehensive Cancer Network, Inc 2011, All Rights Reserved. Prostate cancer v.1. 2011. Accessed April 20, 2011. Available at URL address: http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
39. National Comprehensive Cancer Network[®] (NCCN). NCCN GUIDELINES[™] Clinical Guidelines in Oncology[™]. © National Comprehensive Cancer Network, Inc 2010, All Rights Reserved. Prostate cancer

early detection v.2.2010. Accessed April 20, 2011. Available at URL address:
http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

40. National Institute for Health and Clinical Excellence (NICE). High-intensity focused ultrasound for prostate cancer. Interventional procedure guidance 118. Issue date: March 2005. Accessed April 20, 2011. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=download&o=31190>
41. National Institute for Health and Clinical Excellence (NICE). Prostate cancer. Diagnosis and treatment. NICE Clinical Guideline 58. London, UK: NICE; February 2008. Accessed April 20, 2011. Available at URL address: <http://www.nice.org.uk/>
42. [No authors listed]. Prostate-specific antigen (PSA) best practice policy. American Urological Association (AUA). Oncology (Williston Park). 2000 Feb;14(2):267-72, 277-8, 280 passim.
43. Patel RR, Arthur DW. The emergence of advanced brachytherapy techniques for common malignancies. Hematol Oncol Clin North Am. 2006 Feb;20(1):97-118.
44. Prostate Cancer Research Institute (PCRI). Tranrectal HIFU: The Next Generation? August 2008. Accessed April 19, 2011. Available at URL address: http://www.prostate-cancer.org/education/novelthr/Chinn_TransrectalHIFU.html
45. Rebillard X, Soulié M, Chartier-Kastler E, Davin JL, Mignard JP, Moreau JL, et al.; Association Francaise d'Urologie. High-intensity focused ultrasound in prostate cancer; a systematic literature review of the French Association of Urology. BJU Int. 2008 May;101(10):1205-13. Epub 2008 Mar 4.
46. Rove KO, Sullivan KF, Crawford ED. High-intensity focused ultrasound: ready for primetime. Urol Clin North Am. 2010 Feb;37(1):27-35, Table of Contents. Review.
47. Schaffzin DM, Wong WD. Endorectal ultrasound in the preoperative evaluation of rectal cancer. Clin Colorectal Cancer. 2004 Jul;4(2):124-32.
48. Shetty S. Transrectal ultrasound of the prostate (TRUS). eMedicine. Last updated 2011 March 29. Accessed April 19, 2011. Available at URL address: <http://www.emedicine.com/med/topic3477.htm>
49. Shoji S, Nakano M, Nagata Y, Usui Y, Terachi T, Uchida T. Quality of life following high-intensity focused ultrasound for the treatment of localized prostate cancer: a prospective study. Int J Urol. 2010 Aug;17(8):715-9. Epub 2010 May 31.
50. Singh AK, Kruecker J, Xu S, Glossop N, Guion P, et al. Initial clinical experience with real-time transrectal ultrasonography-magnetic resonance imaging fusion-guided prostate biopsy. BJU Int. 2008 Apr;101(7):841-5. Epub 2007 Dec 5.
51. Smith JA Jr, Scardino PT, Resnick MI, Hernandez AD, Rose SC, Egger MJ. Transrectal ultrasound versus digital rectal examination for the staging of carcinoma of the prostate: results of a prospective, multi-institutional trial. J Urol. 1997 Mar;157(3):902-6.
52. Song JM, Kim CB, Chung HC, Kane RL. Prostate-specific antigen, digital rectal examination and transrectal ultrasonography: a meta-analysis for this diagnostic triad of prostate cancer in symptomatic korean men. Yonsei Med J. 2005 Jun 30;46(3):414-24.
53. Stucchi AF, Aarons CB, Becker JM. Surgical approaches to cancer in patients who have inflammatory bowel disease. Gastroenterol Clin North Am. 2006 Sep;35(3):641-73.
54. Thompson I, Thrasher JB, Aus G, Burnett AL, Canby-Hagino ED, Cookson MS, et al; AUA Prostate Cancer Clinical Guideline Update Panel. (Prostate Cancer Clinical Guidelines Panel, American Urological Association [AUA]). Guideline for the management of clinically localized prostate cancer [clinical practice guideline]. 2007. Reviewed and validity confirmed 2009. Accessed April 19, 2011. Available at URL address: <http://www.auanet.org/>

55. Uchida T, Ohkusa H, Yamashita H, Shoji S, Nagata Y, Hyodo T, Satoh T. Five years experience of transrectal high-intensity focused ultrasound using the Sonablate device in the treatment of localized prostate cancer. *Int J Urol*. 2006a Mar;13(3):228-33.
56. Uchida T, Ohkusa H, Nagata Y, Hyodo T, Satoh T, Irie A. Treatment of localized prostate cancer using high-intensity focused ultrasound. *BJU Int*. 2006b Jan;97(1):56-61.
57. Uchida T, Baba S, Irie A, Soh S, Masumori N, Tsukamoto T, et al. Transrectal high-intensity focused ultrasound in the treatment of localized prostate cancer: a multicenter study. *Hinyokika Kyo*. 2005 Oct;51(10):651-8.
58. Uchida T, Sanghvi NT, Gardner TA, Koch MO, Ishii D, Minei S, et al. Transrectal high-intensity focused ultrasound for treatment of patients with stage T1b-2n0m0 localized prostate cancer: a preliminary report. *Urology*. 2002 Mar;59(3):394-8.
59. U.S. Preventive Services Task Force. Screening for Prostate Cancer: Clinical Summary of U.S. Preventive Services Task Force Recommendation. AHRQ Publication No. 08-05121-EF-3, August 2008. Agency for Healthcare Research and Quality, Rockville, MD. Accessed April 19, 2011. Available at URL address: <http://www.ahrq.gov/clinic/uspstf08/prostate/prostatesum.htm>
60. Wasserman NF. Benign prostatic hyperplasia: a review and ultrasound classification. *Radiol Clin North Am*. 2006 Sep;44(5):689-710.
61. Wein AJ, Kavoussi LR, Novick AC, Partin AW, Peters CA, editors. *Wein: Campbell-Walsh Urology*. 9th ed. W. B. Saunders. Philadelphia, PA; 2007.
62. Wilt TJ, Shamliyan T, Taylor B, et al. Comparative effectiveness of therapies for clinically localized prostate cancer. Comparative Effectiveness Review No. 13. (Prepared by Minnesota Evidence-based Practice Center under Contract No. 290-02-00009.) Rockville, MD: Agency for Healthcare Research and Quality (AHRQ); February 2008.
63. Winawer S, Fletcher R, Rex D, Bond J, Burt R, Ferrucci J, et al. Gastrointestinal Consortium Panel. Colorectal cancer screening and surveillance: clinical guidelines and rationale-Update based on new evidence. *Gastroenterology*. 2003 Feb;124(2):544-60.
64. Yamada T, Alpers DH, Kaplowitz N, Laine L, Owyang C, Powell DW, et al, editors. *Transrectal ultrasonography*. Textbook of gastroenterology. 4th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2003. Ch. 154.
65. Zelefsy MJ, Eastham JA, Sartor OA, Kantoff P. Cancer of the prostate. DeVita, Hellman, and Rosenberg's cancer: principles & practice of oncology. 8th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2008. Section 6.

Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	6/15/2008	0344	Transrectal Ultrasound (TRUS)

“CIGNA”, “CIGNA HealthCare” and the “Tree of Life” logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company or CIGNA Health and Life Insurance Company.