A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

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<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2018</th>
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<td>Policy Name: Scrotal Ultrasonography</td>
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<td>☒ New Policy*</td>
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<td>☐ Annual Review – No Revisions</td>
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<td>*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:</td>
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**CPB 0532 Scrotal Ultrasonography**

Policy is new to Aetna Better Health of Pennsylvania.

<table>
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<tr>
<th>Name of Authorized Individual (Please type or print):</th>
<th>Signature of Authorized Individual:</th>
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<tbody>
<tr>
<td>Dr. Bernard Lewin, M.D.</td>
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[Signature]
Aetna considers scrotal ultrasonography medically necessary for any of the following conditions:

- Detection and characterization of scrotal mass lesions/tumors; or
- Detection of undescended (cryptorchid) testes in either of the following:
  
  (i) to look for gonads or a uterus in a phenotypically male infant with bilateral non-palpable testes (to evaluate the possibility of disorder of sexual development); and (ii) in obese boys, in whom intracanalicular testes may be difficult to palpate and would change the surgical approach (from laparoscopic to inguinal); or
- Diagnosis of suspected testicular torsion; or
- Evaluation of hydroceles; or
- Evaluation of infertile men; or
• Evaluation of scrotal pain and/or swelling (acute scrotal symptoms); or
• Evaluation of scrotal injury/trauma; or
• Evaluation of varicoceles.

Aetna considers scrotal ultrasonography experimental and investigational for surveillance of testicular microlithiasis in the absence of additional risk factors (e.g., a history of cryptorchidism or testicular atrophy (less than 12 ml), previous testicular cancer).

Aetna considers scrotal ultrasonography experimental and investigational for all other indications because of insufficient evidence of its clinical value for other indications.

Background

Scrotal ultrasonography has been demonstrated to have a clinically significant impact on urologists’ diagnoses of scrotal abnormalities and disorders. Scrotal ultrasound is characterized by high sensitivity in the detection of intra-scrotal abnormalities and is a very good mode for differentiating testicular from para-testicular lesions. The main indication for color Doppler ultrasound (which can reveal scrotal blood flow) is assessment of acute scrotal symptoms (pain or swelling), especially in the diagnosis of suspected testicular torsion. The vast majority of boys who exhibit acute scrotal symptoms have non-surgical conditions, usually epididymitis or torsion of the appendix testis. Since the clinical appearances of these conditions are often similar to that of testicular torsion, imaging is frequently performed to help with diagnosis. In fact, color Doppler ultrasound is the method of choice for imaging scrotal organs, and allows more objective and precise assessment of varicoceles. Varicoceles can be diagnosed by showing intra-scrotal veins larger than 2 mm. It has also been shown that color Doppler ultrasound is more accurate and reliable than
physical examination in conjunction with gray-scale ultrasound (which is non-specific and can’t be used to diagnose testicular torsion) in the differential diagnosis of acute scrotum.

Patients with hydroceles large enough to prevent adequate palpation of the testes should undergo scrotal ultrasound. Sonographic identification of calculi in the hydroceles may prevent further imaging and unnecessary surgery. Color Doppler ultrasound is also used in the evaluation of traumatized scrotum. Testis rupture must be diagnosed rapidly and color Doppler ultrasound can be used to evaluate perfusion of the testis. The prediction of testicular viability following trauma is essential for proper treatment. Other indications for scrotal ultrasonography are detection of undescended (cryptorchid) testes, and evaluation of infertile men. It should be noted that intra-abdominal testes can not be located with ultrasound. Routine scrotal ultrasound has been reported to provide valuable information in the diagnostic evaluation of infertile men and substantially more pathological conditions are detected compared to clinical palpation. The high prevalence of testicular malignancies underscores the importance of routine scrotal ultrasonography in infertile men.

Serter et al (2006) noted that testicular microlithiasis (TM) is a rare, usually asymptomatic finding of the testes associated with various genetic anomalies and infertility. It is believed that TM is strongly associated with testicular tumor. In a prospective study, these researchers determined the prevalence of TM in an asymptomatic population by means of ultrasound screening. Healthy male volunteers (17 to 42 years old) were recruited from the annual Army Reserve Officer Training Corps training camp at Manisa, Turkey. A screening genito-urinary history was obtained and a physical examination and screening scrotal ultrasound scan were performed. All men diagnosed with TM underwent complete clinical evaluations, physical examinations and determination of tumor markers. A total of 53 men with TM were identified from the 2,179 ultrasound scans, giving a prevalence of TM of
2.4 % in this asymptomatic population. The age (mean ± SD) of subjects with TM was 23.9 ± 4.2 years (range of 20 to 31 years). The authors concluded that these findings suggested that there is no significant association between TM and testicular cancer, although it is difficult to rule out such an association without further studies with a longer follow-up period.

DeCastro and colleagues (2007) stated that TM is an imaging entity of the testicle with questionable significance as a marker for testicular cancer. In 2001 these investigators reported on a large prospective screening study establishing the prevalence of TM to be 5.6 % in a healthy asymptomatic population of Army volunteers 18 to 35 years old. In contrast, testicular cancer develops in only 5 of 100,000 men. Two-year follow-up of 63 of the 84 patients with TM showed that none of these men had testicular cancer or scrotal masses. Here these researchers reported he 5-year follow-up in this cohort of men with TM at risk for testicular cancer. According to the original parameters of the screening study these investigators performed a history, genito-urinary examination and scrotal ultrasound on 1,504 healthy army volunteers 18 to 35 years old. Testicular microlithiasis was defined as greater than 6 echogenic signals found on ultrasound. They identified 84 patients with TM (5.6 %). These men were entered into the follow-up phase of the study and instructed regarding testicular self-examination and the need for follow-up. They were told to report any changes in their examination or a finding of testicular mass or cancer. Five years after the initial screening study, the authors attempted to contact all remaining 84 men by e-mail, standard mail and telephone. Of the original 84 men with TM identified in the original screening study, 63 have been contacted via e-mail and by telephone (75 %). Of the 63 subjects, a mixed germ cell tumor developed in 1 patient 64 months after the initial screening study. Compared to the incidence of testicular cancer in the general population the odds ratio of developing testicular cancer in this study population was 317 (95 % confidence interval [CI]: 36 to
The authors concluded that testicular cancer will not develop in the majority of men with TM (98.4%) during a 5-year follow-up interval. They believed that an intensive screening program for men with TM is not cost-effective and would do little to improve outcomes associated with testicular cancer. These investigators continued to recommend testicular self-examination in men at risk.

In a retrospective study, Chen and colleagues (2010) determined the incidence of TM in Taiwanese males who were referred for scrotal ultrasonography (US) and evaluated the association between TM and cancer, with state-of-the-art equipment. A total of 513 males who underwent scrotal US in a period of 7 months were included in this study. The US images and charts of each patient were reviewed to determine the presence of TM and note relevant clinical information. The data for all 513 patients were analyzed. Their age was 0 to 91 years (mean of 54.3 years). The overall incidence of TM was 14.4% (74/513); 6.2% (32/513) had classic TM, and 8.2% had limited TM. The incidence of testicular cancer in this population was 1.6% (8/513). Six of 8 (75%) patients who had testicular cancer at presentation had classic TM or limited TM. There was a significant difference (p < 0.01) between the rate of malignancy in subjects with TM (6/74) and that in subjects without TM (2/439). The authors concluded that the incidence of TM in Taiwanese people may be higher than previously reported, which may be due to the difference in methodology and increased awareness of the US findings. Moreover, they stated that although there was a significant difference in the rate of malignancy in males with TM compared with those without TM, the question remains whether TM independently increases the risk of testicular malignancy.

Dutra et al (2011) evaluated the prevalence of TM among pediatric patients with inguino-scrotal affections. Between January 2005 and January 2010, these investigators evaluated, prospectively 1,504 children ranging from 1 to 15 years old. The overall incidence of TM was 10.1% (153/1,504); 5.4% (82/1,504) had classic TM, and 4.7% had limited TM. The incidence of testicular cancer was 0.7% (11/1,504). Eight of 11 (73%) patients who had testicular cancer at presentation had classic TM or limited TM. There was no significant difference between the rate of malignancy in subjects with TM (8/153) and that in subjects without TM (3/1,351). The authors concluded that the incidence of TM in pediatric patients may be lower than previously reported, which may be due to the difference in methodology and decreased awareness of the US findings. Moreover, they stated that although there was no significant difference in the rate of malignancy in males with TM compared with those without TM, the question remains whether TM independently increases the risk of testicular malignancy.
years with inguino-scrotal affections with a high-frequency ultrasound system, which employs a 10-MHz transducer. Testicular microlithiasis was identified in 20 testes of 11 children (0.71 % of 1,504 patients evaluated), through an ultrasound scan. Testicular microlithiasis was found in 5 children with cryptorchidism (3.93 % of 127 patients), 4 children with retractile testes (14.8 % of 27 patients), 1 child with a hypotrophic testis (100 % of 1 patient), and 1 child with inguinal hernia (0.07 % of 1,349 patients). The children with TM were submitted to annual physical examinations and ultrasound evaluations. The authors concluded that TM was a rare condition and occurred in 0.7 % of the subjects studied. The association with cryptorchidism, retractile and hypotrophic testis was significant.

Richenberg et al (2012) stated that ultrasound surveillance of patients with TM has been advocated following the reported association with testicular cancer. These researchers evaluated the evidence supporting such surveillance. Formal literature review identified cohort studies comprising at least 15 patients followed-up for at least 24 months. Combining an institutional audit with the identified studies in a pooled analysis the incidence of new cancers during the surveillance period was evaluated. Literature review identified 8 studies. The authors’ institutional audit comprised 2,656 men referred for scrotal ultrasound. Fifty-one men (1.92 %) with TM were identified, none of whom developed testicular cancer (mean follow-up: 33.3 months). In a combined population of 389 men testicular cancer developed in 4. Excluding 3 who had additional risk factors, only 1 of 386 developed testicular cancer during follow-up (95 % confidence interval: 0.05 5 to 1.45 %). The authors concluded that ultrasound surveillance is unlikely to benefit patients with TM in the absence of other risk factors. In the presence of additional risk factors (a history of cryptorchidism or testicular atrophy, previous testicular cancer) patients are likely to be under surveillance;
nonetheless monthly self-examination should be encouraged, and open access to ultrasound and formal annual surveillance should be offered.

An UpToDate review on “Screening for testicular cancer” (Lin, 2014) states that “Testicular microlithiasis is a common finding during infertility evaluations, but its association with testicular cancer is controversial. Microlithiasis has been detected with scrotal ultrasonography in up to 5 percent of healthy adolescents and young men”.

Shetty et al (2014) examined if there is a consensus regarding the significance of TM and a strategy for managing patients with this condition, among ultrasound practitioners in the United Kingdom (U.K.). An electronic questionnaire was distributed to 1,482 members of the British Medical Ultrasound Society (BMUS), requesting information from ultrasound practitioners involved in scrotal ultrasound about their interpretation of the risk associated with TM and their departmental or personal recommendations for managing patients with this condition. Responses were obtained from 221 BMUS members. Analysis demonstrated a wide variation in the significance attributed to the discovery of TM and the risk of subsequent development of testicular germ cell tumors. There was also great variation in strategies for management of patients with TM, including the need for surveillance ultrasound, among ultrasound practitioners regardless of their job description. The authors concluded that lack of consensus shown by this study highlights significant differences across the U.K. in managing patients with TM and validates the importance of guidance currently being formulated by the European Society of Urogenital Radiology. These researchers believe that this is the first survey conducted among imaging specialists in the U.K. regarding TM and demonstrates that there is currently no uniform practice in managing patients with this condition.
Furthermore, the European Association of Urology’s clinical practice guidelines on “Testicular cancer” (Albers et al, 2011) stated that “In the absence of other risk factors (less than 12 ml (atrophy), maldescent testis), testicular microlithiasis is not an indication for biopsy or further (ultrasound) screening”.

Volokhina and colleagues (2014) noted that there is suggestion that testicular microlithiasis predicts risk of testicular malignancy, especially testicular germ cell tumors. This association remains uncertain. These investigators retrospectively reviewed testicular germ cell tumor occurrence in patients with testicular microlithiasis to assess this association and determined the prevalence of testicular microlithiasis in symptomatic boys. This study was IRB and HIPAA compliant. A total of 2,625 testicular US exams performed on 2,266 children (younger than 19 years of age) in the authors’ institution from 2000 through 2011 were reviewed for presence of testicular microlithiasis and masses. Testicular microlithiasis was defined as presence of 5 or more testicular microcalcifications on a single US image. Incidence of testicular germ cell tumors was calculated in a group of patients with testicular microlithiasis and in a control group without testicular microlithiasis. Relative risk, odds ratio, 90 % and 95 % CI were calculated. A total of 87 patients out of 2,266 had testicular microlithiasis. One child was found to have both testicular germ cell tumor and testicular microlithiasis. In 2,179 children without testicular microlithiasis, 8 had testicular germ cell tumors. Incidence of testicular microlithiasis was 3.8 %. Incidence of testicular germ cell tumors in testicular microlithiasis patients was 1.2 %, and 0.38 % in non-testicular microlithiasis patients. Relative risk of testicular germ cell tumors in testicular microlithiasis patients versus non-testicular microlithiasis patients was 3.13 (90 % CI: 0.55 to 17.76; 95 % CI: 0.40 to 24.76), odds ratio (OR) 3.16 (90 %CI: 0.55 to 18.32; 95 % CI: 0.39 to 25.5). The authors concluded that there is no association between testicular microlithiasis and testicular germ cell tumors. These
investigators had hoped to do a meta-analysis, but only 2 studies had a sufficient case control group of non-testicular microlithiasis patients.

**Testicular Microlithiasis**

Richenberg et al (2015) stated that the subcommittee on scrotal imaging, appointed by the board of the European Society of Urogenital Radiology (ESUR), have produced guidelines on imaging and follow-up in testicular micro-lithiasis (TML). The authors and a superintendent university librarian independently performed a computer-assisted literature search of medical databases: MEDLINE and EMBASE. A further parallel literature search was made for the genetic conditions Klinefelter's syndrome and McCune-Albright syndrome. Proposed guidelines were: follow-up is not advised in patients with isolated TML in the absence of risk factors; annual US is advised for patients with risk factors, up to the age of 55; if TML is found with a testicular mass, urgent referral to a specialist center is advised. The authors concluded that consensus opinion of the scrotal subcommittee of the ESUR is that the presence of TML alone in the absence of other risk factors is not an indication for regular scrotal US, further US screening or biopsy. Ultrasonography is recommended in the follow-up of patients at risk, where risk factors other than microlithiasis are present.

**Undescended (Cryptorchid) Testes**

Kanaroglou et al (2015) stated that there is a limited role for ultrasound in the management of an undescended testicle (UDT). These investigators hypothesized that ultrasound remains over-used by referring physicians; they characterized the trends, patterns, and impact of ultrasound use for UDT and re-affirmed its limited diagnostic value for this indication. The records of boys aged 0 to 18 years with UDT in Ontario, Canada, between 2000 and 2011 were reviewed by using health administrative data housed at the Institute for Clinical
and Evaluative Sciences (ICES). A second review of boys referred to the authors' institution with UDT between 2007 and 2011 was conducted to complement the health administrative data. Trends in frequency, distribution, and costs of ultrasound use were assessed. Time delays between diagnosis and definitive management were compared between the ultrasound and non-ultrasound groups. Using the authors' institutional data, these researchers analyzed demographic patterns of ultrasound use and compared its diagnostic accuracy by using surgical findings as the gold standard.

Ultrasound was used in 33.5% of provincial referrals and 50% of institutional referrals. Children who underwent ultrasound experienced an approximate 3-month delay in definitive surgical management. Ultrasound correctly predicted physical examination findings in only 54% of patients. Physicians in community practice, and those with fewer years in practice, were more likely to order ultrasound. The authors concluded that ultrasound has limited value for the management of UDT but remains widely over-used, with an increasing trend over time. They stated that this practice has negative implications for access to care and cost-containment; wide-spread educational efforts should be undertaken, targeting current and future referring physicians.

Furthermore, an UpToDate review on “Undescended testes (cryptorchidism) in children: Clinical features and evaluation” (Cooper and Docimo, 2015) states that “Imaging is not routinely warranted to locate non-palpable testes. Imaging studies lack the sensitivity and the specificity to alter the need for exploratory surgery. In a systematic review, the sensitivity and specificity of ultrasonography in detecting non-palpable testes were 45 and 78%, respectively. In contrast, the sensitivity and specificity of exploratory surgery are nearly 100%.

Imaging may be necessary to evaluate conditions in the differential diagnosis or for surgical planning. As examples:
• Ultrasonography may be indicated to look for gonads or a uterus in a phenotypically male infant with bilateral non-palpable testes (to evaluate the possibility of disorder of sexual development).
• Ultrasonography may be warranted in obese boys, in whom intra-canalicular testes may be difficult to palpate and would change the surgical approach (from laparoscopic to inguinal). In a systematic review of the literature, the accuracy of ultrasonography in identifying inguinal or scrotal testes was 92%, but the included studies were of poor quality and lacked important clinical information (e.g., position of contralateral testis, associated clinical findings, etc.).

Testicular Torsion

McDowall and colleagues (2018) stated that a positive whirlpool sign (WS) is defined as the presence of a spiral-like pattern when the spermatic cord is assessed during US, using standard, high-resolution US (HRUS) and/or color Doppler sonography (CDS), in the presence of testicular torsion (TT). These investigators evaluated the validity and accuracy of this sign by performing a comprehensive systematic literature review and meta-analysis. In accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines, a comprehensive literature search was performed (August, 2017), using the following databases: BMJ Best Practice, Cochrane Library, Embase, PubMed, Scopus, and Web of Science. Selected studies were further assessed for relevance and quality using the Oxford 2010 Critical Appraisal Skills Program (CASP). Of the studies assessed, a total of 723 participants were included, with a mean of 72.3 (SD 71.9) participants. Of the participants, 226 (31.3 %) were diagnosed with TT. Meta-analysis of the studies that provided sufficient data resulted in a pooled sensitivity and specificity of the WS of 0.73 (95 % CI: 0.65 to 0.79) and 0.99 (95 % CI: 0.92 to 0.99), respectively. Removal of all neonates increased the pooled sensitivity to 0.92 (95 % CI: 0.70 to 0.98) while the
pooled specificity remained almost unchanged at 0.99 (95% CI: 0.95 to 1.00). The estimated summary effect of all studies with sufficient data was 4.34 (95% CI: 1.01 to 7.67; n = 394; p = 0.001). A large degree of heterogeneity was suggested by an I2 statistic of 88.27% (95% CI: 68.60 to 98.68%).

Removal of neonatal subjects increased the estimated summary effect to 5.32 (95% CI: 1.59 to 9.05; n = 375; p = 0.001). The authors concluded that the WS, when correctly diagnosed, may be viewed as a very definitive sign for TT in the pediatric and adult populations; however, its role in neonates is limited.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

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<td>Unspecified injury of external genitals</td>
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The above policy is based on the following references:

28. American Institute of Ultrasound in Medicine; American College of Radiology; Society of Radiologists


37. Lin KW. Screening for testicular cancer. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2014.


42. Cooper CS, Docimo SG. Undescended testes (cryptorchidism) in children: Clinical features and evaluation. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed March 2016.


Amendment to
Aetna Clinical Policy Bulletin Number: 0532 Scrotal Ultrasonography

There are no amendments for Medicaid.