

Subject: Transrectal Ultrasonography

Guideline #: CG-MED-45

Status: Reviewed

Publish Date: 04/10/2024

Last Review Date: 02/15/2024

Description

This document addresses the use of transrectal ultrasonography in the diagnosis, staging, and management of conditions involving the prostate, rectum, uterus, vaginal canal and surrounding tissues.

Note: Please see the following related document for additional information:

- [CG-SURG-98 Prostate Biopsy using MRI Fusion Techniques](#)
- [SURG.00107 Prostate Saturation Biopsy](#)

Clinical Indications

Medically Necessary:

Transrectal ultrasonography (TRUS) is considered **medically necessary** for **any** of the following indications:

- To guide prostate biopsy when prostate cancer is suspected based on abnormal digital rectal examination (DRE) **or** prostate-specific antigen (PSA) level greater than 3.0 ng/ml **or** medical history; **or**
- To guide application of cryotherapy or brachytherapy for treatment of prostate cancer; **or**
- To evaluate and stage prostate cancer or rectal cancer; **or**
- To evaluate and guide treatment for **any** of the following:
 - Anal, rectal, or peri-rectal abscess, tumors, fistula, or anal sphincter dysfunction; **or**
 - Infertility associated with ejaculatory duct obstruction; **or**
 - Hematospermia (hemospermia); **or**
 - Benign prostatic hyperplasia (BPH), prostate abscess, prostatic calculi, or prostatitis; **or**
 - Pelvic masses, pelvic inflammatory conditions, or rectovaginal endometriosis; **or**
 - Suspected congenital anomalies of the prostate, rectum, or surrounding tissue (for example: uterus, or vaginal canal).

Not Medically Necessary:

Transrectal ultrasonography (TRUS) is considered **not medically necessary** when criteria are not met and for **all** other indications, including but not limited to use as a primary screening test for prostate cancer.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

76872 Ultrasound, transrectal

ICD-10 Diagnosis

C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0-C21.8	Malignant neoplasm of anus and anal canal
C61	Malignant neoplasm of prostate
C7A.026	Malignant carcinoid tumor of the rectum
C76.3	Malignant neoplasm of pelvis
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 rectosigmoid junction, rectum, anus and anal canal
D07.5	Carcinoma in situ of prostate
D12.7-D12.9	Benign neoplasm of rectosigmoid junction, rectum, anus and anal canal
D29.1	Benign neoplasm of prostate
D3A.026	Benign carcinoid tumor of the rectum
D37.5	Neoplasm of uncertain behavior of rectum
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D40.0	Neoplasm of uncertain behavior of prostate
D49.0	Neoplasm of unspecified behavior of digestive system
D49.59	Neoplasm of unspecified behavior of other genitourinary organs
K60.0-K60.5	Fissure and fistula of anal and rectal regions
K61.0-K61.4	Abscess of anal and rectal regions
K62.0-K62.9	Other diseases of anus and rectum
N40.0-N40.3	Benign prostatic hyperplasia
N41.0-N41.9	Inflammatory diseases of prostate
N42.0-N42.9	Other and unspecified disorders of prostate
N46.01-N46.9	Male infertility
N70.01-N77.1	Inflammatory diseases of female pelvic organs

N80.4	Endometriosis of rectovaginal septum and vagina
N82.3	Fistula of vagina to large intestine
Q42.0-Q42.9	Congenital absence, atresia and stenosis of large intestine
Q43.0-Q43.9	Other congenital malformations of intestine
Q52.0-Q52.9	Other congenital malformations of female genitalia
Q55.0-Q55.9	Other congenital malformations of male genital organs
R15.0-R15.9	Fecal incontinence
R19.00-R19.09	Intra-abdominal and pelvic swelling, mass and lump
R19.8	Other specified symptoms and signs involving the digestive system and abdomen
R36.1	Hematospermia
R97.20-R97.21	Elevated prostate specific antigen (PSA)
Z85.040-Z85.048	Personal history of malignant neoplasm of rectum, rectosigmoid junction, and anus
Z85.46	Personal history of malignant neoplasm of prostate
Z87.430	Personal history of prostatic dysplasia

When services are Not Medically Necessary:

For the procedure code listed above when criteria are not met or for all other diagnoses not listed.

Discussion/General Information

Transrectal ultrasonography (TRUS), also called endorectal ultrasound (ERUS), is an imaging procedure used in the diagnosis, staging, and management of conditions involving the prostate, rectum, and surrounding tissues. TRUS has both diagnostic and therapeutic indications. The brief outpatient procedure involves the use of a small lubricated probe inserted into the rectum that sends out high-energy sound waves. These sound waves bounce off internal tissues or organs, making echoes that form a picture of body tissue called a sonogram. While the probe may be temporarily uncomfortable, TRUS is essentially a painless procedure.

Prostate Cancer

Prostate cancer is the most common cancer found in American men. The American Cancer Society (2023) estimated that in 2023 there would be 268,490 new cases of prostate cancer and 34,700 disease-related deaths from prostate cancer in the United States.

Primary screening test

An American College of Preventive Medicine (ACPM) (Lim, 2008) position statement stated:

The principal screening tests for the detection of asymptomatic prostate cancer are the DRE and serum PSA levels. Transrectal ultrasound (TRUS) is no longer considered a first-line screening test for prostate cancer but does play a role in the investigation of patients with abnormal DRE or PSA when guided biopsies are required.

An American Urological Association (AUA) clinical guideline (Carter, 2013) stated that early detection of prostate cancer is driven by PSA-based screening followed by TRUS biopsy for diagnostic confirmation; however, PSA testing can generate a significant number of false positive results due to low specificity. The AUA referenced the use of a 3.0 ng/mL cut off point as used in the multicenter European Randomized Study of Screening for Prostate Cancer (ERSPC), estimating that PSA screening at this level will correctly predict the presence of prostate cancer in about 1 of every 2 (TRUS) biopsies (Schroder, 2009). The guideline recognized PSA testing as the primary screening test to assist in informed decision-making concerning the need for TRUS prostate biopsy or repeat biopsy. The AUA further recommended that for men ages 70 to 75 with a PSA of < 3.0 ng/mL, further screening may not be needed, based on the estimated lifetime probability of prostate cancer-related death at 7%, with the frequency increasing with age, as reported in an observational study by Schaeffer and colleagues (2009).

Detection, Staging and Surveillance

The gold standard in the diagnosis of prostate cancer is a prostate biopsy. Contemporary prostate biopsy relies on spring-loaded biopsy devices that are either digitally guided or guided via ultrasound. TRUS guidance is the most frequently used method of directing prostate needle biopsy (Bjurlin, 2014).

The American College of Radiology (ACR) Appropriateness Criteria[®] for pretreatment detection, staging, and surveillance of prostate cancer (ACR, 2022) recommended TRUS-guided systematic needle biopsy of the prostate gland as the standard procedure for the diagnosis of prostate cancer. For monitoring of lower-risk prostate cancer, the ACR criteria stated "serial TRUS-guided systemic remains a standard component of active surveillance regimens." An ACR Appropriateness Criteria for post-treatment follow-up of prostate cancer (ACR, 2022) stated:

TRUS-guided biopsy can be performed in a systematic manner, often done as a random sampling of the areas that most likely harbor recurrence: the vesicourethral anastomosis, retrovesical region, and seminal vesicle beds...The yield for detecting local recurrent tumor with TRUS with needle biopsy rises significantly with serum PSA levels.

The NCCN CPG for management of early detection of prostate cancer (NCCN, V2.2023) in its recommendations for further evaluation and indications for biopsy recommended TRUS-guided biopsy or transperineal-guided biopsy with or without MRI targeting. (Category 2A): The guideline noted that clinical randomized controlled trials used PSA thresholds to prompt biopsy and that PSA cutpoints for biopsy varied, stating:

Although a serum PSA of 2.5 ng/mL has been used by many, a level of 3 ng/mL is supported by the trials and would more robustly limit the risk of overdiagnosis. A higher threshold of 4 ng/mL is recommended for patients who choose to continue PSA screening past the age of 75 years. However, some panel members did not recommend limiting the option of biopsy to pre-specified PSA thresholds, noting that there are many other factors (eg, age, ancestry, race, family history, PSA kinetics) that should also inform the decision to perform biopsy (NCCN, V2.2023).

For management of benign biopsy results, the early detection of prostate cancer guideline recommended "repeat prostate biopsy, based on risk." For management of high-grade prostatic intraepithelial neoplasia (HGPIN) biopsy (focal) results, the guideline recommended follow-up with: 1) PSA and DRE at 6 to 24 month intervals; and, 2) repeat TRUS-guided prostate biopsy based on risk, considering "...it is well known that a negative biopsy does not preclude a diagnosis of prostate cancer on subsequent biopsy" (both 2A recommendation). Current tools to calculate risk combine factors including age, family history, race, DRE and PSA (that is, medical history) to aid in the decision of whom to biopsy. For management of HGPIN multifocal results, the guideline recommends that repeated biopsy with relative increased sampling of the atypical site be considered.

Transperineal prostate brachytherapy is considered a treatment option for clinically localized prostate cancer. TRUS is used as an effective guide prior to brachytherapy to determine the number of needles and corresponding radioactive seeds, the isotope, and the

isotope strength for the procedure and during the procedure to execute the placement of the radioactive seeds into the prostate (Davis, 2012).

Rectal Cancer

The ACS (2023) estimated that, in 2023, there will be 46,050 new cases of rectal cancer diagnosed in the United States. Pretreatment local staging evaluation for rectal cancer is mainly accomplished through physical examination, endoscopy, CT scans, MRI, and TRUS.

The ACR Appropriateness Criteria for staging of colorectal cancer, states that imaging modalities including TRUS, CT, and MRI have all been extensively evaluated in the initial staging of colorectal cancer (ACR, 2021). TRUS has been the gold standard for T-stage evaluation of rectal cancer with substantive evidence to support its use:

TRUS is able to differentiate the layers of the rectal wall and provides high accuracy in detecting and characterizing tumors within the superficial layers of the rectal wall. Reported accuracies range between 80% and 97% for T-stage determination (Yimei, 2012). The T-stage accuracy for TRUS (84.6%) is far superior to that of CT (70.5%) (Ju, 2009). Evaluation of the extent of the tumor infiltration into the mesorectum (differentiating minimal from advanced T3 tumors and minimal T3 from T2 tumors) is of clinical interest in determining the need for neoadjuvant treatment but remains a challenge for TRUS (Jurgensen, 2011; Badger, 2007). Although TRUS performs better than MRI for T-1 tumors, similar for T2-3, it may be less accurate in characterizing locally advanced tumors (T4) with a tendency to understage (Fernandez-Esparrach, 2011).

The sensitivity of TRUS is limited in the detection of lymph node involvement to mesorectal nodes in the vicinity of the tumor. Sensitivity ranges from 45%-74% (Lin, 2011; Ravizza, 2011) and overall accuracy ranges from 62%-83% (Low, 2008). TRUS, however, has not been shown to be predictive of the histology of the visualized lymph nodes (Li, 2015). The ACR criteria states:

Many lymph nodes measuring < 5 millimeters in diameter have associated micrometastases, and some early-stage T1 and T2 tumors are likely to have lymph node micrometastases missed by TRUS. This may be responsible for the high rate of pelvic recurrence within this patient group (Landmann, 2007). Lymph nodes along the superior rectal vessels and outside the mesorectal fascia along the internal iliac and obturator nodal stations (ie, lateral pelvic side wall) also cannot be assessed with TRUS. This can also be clinically important; 1 series showed that 27% of the rectal cancer study cohort (Dukes class C; T2-T4 tumors) demonstrated positive lateral lymph node involvement, with a small percentage with lateral lymph node involvement only (4%) (Moriya, 1997). TRUS similarly is limited in evaluating lateral lymph nodes.

The American Society of Colon and Rectal Surgeons (ASCRS) practice parameters for the treatment of rectal cancer (Monson, 2013) recommended that clinical staging of primary rectal tumors be performed by ERUS or dedicated high resolution rectal MRI. ERUS may be better for distinguishing between T1 and T2 tumors; although, ERUS is less accurate in the assessment of large bulky lesions (T4 stage accuracy of 44-50%) and can pose difficulties in evaluating stenotic lesions.

For the surveillance of individuals after curative resection with anastomosis for rectal cancer, the ASCRS practice guidelines (Steele, 2015) recommend proctosigmoidoscopy, with or without ERUS, "every 6 to 12 months for 3 to 5 years for those undergoing low anterior resection, and every 6 months for 3 to 5 years for those with a higher risk of local recurrence." Surveillance of rectal cancer using ERUS may be more sensitive in detecting locoregional recurrence, although the impact on overall survival is unknown. For surveillance of individuals who have undergone transanal local excision of rectal cancer, proctosigmoidoscopy, with or without ERUS, is recommended every 6 months for 3 to 5 years.

Other Indications

TRUS is a clinically useful tool for evaluation of other conditions involving the prostate, rectum, and surrounding tissues and has been used in the evaluation of congenital anomalies. The procedure can be performed quickly and is well-tolerated by individuals with no exposure to radiation. TRUS can identify structural abnormalities of the prostate gland, seminal vesicles, and spermatic cord, and guide biopsies if suspicious abnormalities are identified in those organs. Additional uses of TRUS include assessment of the prostate gland and prostate volume before medical management or minimally invasive surgical procedures for BPH (for example, transurethral microwave thermotherapy [TUMT]) (Wasserman, 2006), and, to evaluate other conditions of the prostate including symptoms of prostatitis, suspected abscess, or prostatic calculi. An AUA guideline on the management of BPH (2018) stated:

Clinicians should consider assessment of prostate size and shape via abdominal or transrectal ultrasound, or cystoscopy, or by preexisting cross-sectional imaging (i.e. magnetic resonance imaging [MRI]/ computed tomography [CT]) prior to surgical intervention for LUTS attributed to BPH. (Clinical Principle)

In evaluation of infertility, the male partner is involved in approximately one-third of the cases. TRUS, with or without seminal vesicle aspiration and seminal vesiculography, is considered as an initial minimally invasive diagnostic test to identify ejaculatory duct obstruction in azoospermic men with low ejaculate volumes and bilateral palpable vasa (Abdulwahed, 2013; ASRM, 2012; Chen, 2014; Gangel, 2002). In men with ejaculatory duct obstruction demonstrated by TRUS, the findings may direct testis biopsy if needed to confirm normal spermatogenesis. TRUS is also used to rule out seminal vesicular cysts, Müllerian cysts, or utricular cysts.

Hemospermia (hematospermia), defined as blood in the semen, is a common condition that is infrequently associated with significant pathology. Hemospermia may be the result of calcifications or calculi in the prostate, ejaculatory ducts, or seminal vesicles, an infection (prostatitis), benign prostatic hyperplasia, prostate cancer, prostatic cysts, conditions of the urethra (urethritis and other lesions), congenital and acquired seminal vesicle lesions, systemic disorders, or trauma. TRUS is considered the imaging procedure of choice for evaluation of men with persistent hemospermia (lasting more than 1 month) to distinguish idiopathic from secondary hemospermia when the bleeding cause is known or suspected (for example, bladder, prostate or systemic malignant pathology) and an accurate diagnosis dictates the extent of further evaluation and treatment of the condition. TRUS is sensitive for detecting a variety of abnormalities that may involve the prostate gland and seminal tract in the setting of hemospermia, reportedly demonstrating abnormalities in 82% to 95% of men with hemospermia. (ACR, 2016a; Manohar, 2008; Yagci, 2004; Zhao, 2012). Xing and colleagues (2012) reported on a prospective trial of 106 subjects with persistent hemospermia and found the diagnostic accuracy of TRUS and transurethral seminal vesiculoscopy was 45.3% and 74.5%, respectively, although the diagnostic accuracy was higher when both modalities were combined.

Endometriosis is a condition in which tissue similar to that normally lining the uterus is found outside the uterus, usually on the ovaries, fallopian tubes, and other pelvic structures, and affects 10% to 15% of women of reproductive age. TRUS has been used for assessing the extent of endometriosis and is accurate in the diagnosis and management of endometriosis in the rectovaginal septum (Nisenblat, 2016). The sensitivity and specificity of preoperative imaging with TRUS in defining the extent of endometrial lesions and predicting rectovaginal septum or rectosigmoid infiltration has been confirmed in prospective and retrospective case series (Abrão, 2004; Delpy, 2005; Doniec, 2003; Fedele, 1998; Kruse, 2012; Ribeiro, 2008).

TRUS and TRUS-guided transrectal biopsy have been used with or without other imaging modalities including pelvic or transvaginal ultrasonography to evaluate the extension of gynecologic-related pelvic masses, including cervical, retroperitoneal, ovarian, or uterine masses, into surrounding tissues and to guide further treatment (such as drainage of deep pelvic and perirectal abscesses) (Giede, 2004; Lorentzen, 2011; Nielsen, 2004). When transvaginal scanning is not feasible or contraindicated, TRUS has been used as an alternative to transvaginal ultrasonography to evaluate conditions of the female pelvis (Fleischer, 1995; Timor-Tritsch, 2003). For women with endometrial cancer in the presence of atrophic or post-radiation vaginal stenosis, TRUS has been used to define the extent of the cancer and guide fine-needle aspiration biopsy of recurrent tumors (Squaillaci, 1988).

Müllerian agenesis is an embryologic underdevelopment of the Müllerian duct resulting in failure of the uterus, vagina, or both to develop during embryonic growth. It is also referred to as Müllerian aplasia, Mayer-Rokitansky-Küster-Hauser syndrome, or vaginal agenesis and has an incidence of 1 per 4,500-5,000 females. The vaginal canal is shortened and may appear as a dimple below the urethra. Uterine horns or a single midline uterine remnant may be present. Initial evaluation may include transrectal two-dimensional or three-dimensional ultrasound to assess the presence of a midline uterus.

Structural abnormalities of the anal sphincter, the rectal wall, and the puborectalis muscle can be identified in detail with TRUS. TRUS has been used as an alternative to MRI evaluation of anal, rectal, and perianal abscesses and fistulas, and benign tumors. The majority of TRUS studies have focused on individuals without Crohn's disease. The rigid nature of the TRUS probe, however, may prevent good acoustic coupling higher in the rectum, preventing the interpretation of higher fistula tracks in the evaluation of these conditions in individuals with or without Crohn's disease. For management of severe Crohn's disease, an American College of Gastroenterology (ACG) (Lichtenstein, 2009) practice guideline recommends evaluation of an abdominal mass/abscesses or perianal complications with serial imaging, including endoscopic ultrasonography, CT, or MRI, prior to consideration of surgical intervention.

TRUS is also useful for establishing a diagnosis in individuals in whom a medical history or manometric findings suggest sphincter dysfunction or occult sphincter injury, and is currently the simplest, most reliable, and least invasive test for defining anatomic defects in the external and internal anal sphincters. For persons with suspected fecal incontinence, an ACG practice guideline (Rao, 2004) recommends imaging with endosonography to assess and define structural defects of the external and internal anal sphincter muscle for the presence of scarring, loss of muscle tissue, and other local pathology.

A joint guideline from the ACR, the American Institute of Ultrasound in Medicine (AIUM) and the Society of Radiologists in Ultrasound (SRU) (2020) stated that the indications for the transrectal approach to ultrasound of the prostate include, but are not limited to:

1. Guidance for biopsy in the presence of an abnormal digital rectal examination or elevated PSA or a suspicious prostatic lesion detected on MR. This includes use of transrectal ultrasound (TRUS) biopsy as part of the TRUS/MRI fusion technique;
2. Assessment of prostate volume before medical, surgical, or radiation therapy and to calculate PSA density;
3. Real-time guidance for the placement of brachytherapy seeds;
4. Real-time guidance for the placement of peri-prostatic spacer material
5. Assessment of lower urinary tract symptoms;
6. Assessment of congenital anomalies;
7. Infertility including azoospermia and a low ejaculatory volume;
8. Hematospermia;
9. Evaluation for suspected recurrence in the prostatectomy bed in patients who have undergone prostatectomy; and
10. Ejaculatory dysfunction or painful ejaculation.

Definitions

Biopsy: The removal of a sample of tissue for examination under a microscope for diagnostic purposes.

Digital rectal examination (DRE): An examination of the lower rectum where the medical practitioner uses a gloved, lubricated finger to check for abnormalities of the prostate.

Prostate: A walnut-shaped gland in men that extends around the urethra at the neck of the urinary bladder and supplies fluid that goes into semen.

Prostate-specific antigen (PSA): A blood test that measures the amount of a specific prostate-related protein in blood, used to screen for prostate cancer and other conditions. A high PSA level in the blood has been linked to having prostate cancer as well as several other benign prostate conditions.

Transrectal ultrasound (TRUS): A procedure in which sound waves produced by a probe inserted into the rectum bounce off internal tissues or organs and make echoes to form a picture of body tissue called a sonogram.

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Transrectal Ultrasound

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion, References, and Websites sections.
Reviewed	02/16/2023	MPTAC review. Updated the Discussion, References, and Websites sections.
Revised	02/17/2022	MPTAC review. Updated the Clinical Indications section. Created separate indication for hematospermia and infertility. Removed "male" from "male infertility" and clarified the specific intent of TRUS. In the "Suspected congenital anomalies of the prostate, rectum, or surrounding tissue", added clarification of surrounding tissue "(for example: uterus or vaginal canal)". Discussion/General Information, Coding and References sections updated.
Reviewed	02/11/2021	MPTAC review. Discussion/General Information and References sections updated. Reformatted Coding section.
Reviewed	02/20/2020	MPTAC review. Discussion/General Information and References sections updated.
Reviewed	03/21/2019	MPTAC review.
Reviewed	03/20/2019	Hematology/Oncology Subcommittee review. Discussion/General Information and References sections updated.
Reviewed	05/03/2018	MPTAC review.
Reviewed	05/02/2018	Hematology/Oncology Subcommittee review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Discussion, References, and Websites for Additional Information sections.
Revised	05/04/2017	MPTAC review.
Revised	05/03/2017	Hematology/Oncology Subcommittee review. Updated formatting in Clinical Indications section. Added "or" between criteria and alphabetized MN statements. Updated Discussion, References, and Websites for Additional Information sections.
	10/01/2016	Updated Coding section with 10/01/2016 ICD-10-CM diagnosis code changes.
Reviewed	05/05/2016	MPTAC review.
Reviewed	05/04/2016	Hematology/Oncology Subcommittee review. Updated Discussion/General Information, References, and Websites for Additional Information sections. Removed ICD-9 codes from Coding section.
Revised	05/07/2015	MPTAC review.
Revised	05/06/2015	Hematology/Oncology Subcommittee review. Format change and clarification to the Not Medically Necessary statement. Updated Description, Discussion, References, and Websites for Additional Information sections.
Revised	05/15/2014	MPTAC review.
Revised	05/14/2014	Hematology/Oncology Subcommittee review. Revised medically necessary criterion addressing the use of TRUS to guide prostate biopsy when prostate cancer is suspected by changing the required PSA level from >10 ng/ml to >3.0 ng/ml. Format change to Description. Updated Discussion, References, and Websites for Additional Information sections.
New	05/09/2013	MPTAC review. Initial document development.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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