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Open Meeting: Controlled Substance Monitoring and Drugs of Abuse Testing

Meeting Date and Time:	October 13, 2020 3:00 p.m. EST
Facilitator:	Dr. Meredith Loveless
Location:	Teleconference
Attendees:	Not to disclose

Dr. Loveless began the meeting at 3:00 p.m. ET.

Polices Reviewed

Controlled Substance Monitoring and Drugs of Abuse Testing

The requirement to utilize a validated questionnaire was removed. The information that was required in a validated questionnaire was part of the routine visit for controlled substances on a regular basis for decision making.

Colon Capsule Endoscopy (CCE)

- CCE allowed for a small capsule to be swallowed and evaluate the colon. CCE is a noninvasive procedure that does not require air inflation or sedation and allowed for minimally invasive and painless colonic evaluation.
- There is less sensitivity and specificity than with traditional optical colonoscopy, which would remain the preferred modality for colonoscopy, but in certain settings when optical colonoscopy is not able to be done and it provides a nice alternative.
- The capsule is swallowed and multiple images are taken. The images are reviewed for that provider to determine if there's any abnormalities. Medicare does not cover training and service would be for diagnostic and surveillance purposes only.
- The policy states that if this is the primary procedure in patients with major risk factors for optical colonoscopy to be performed by someone with a training and experience in the interpretation of the procedure. It is limited to those with positive Fecal Occult Blood Test (FOBT) or Multitargeted Stool DNA (sDNA) test. As a secondary procedure for surveillance when optical colonoscopy was incomplete or the incomplete diagnostic, optical colonoscopy was performed for positive occult blood or Multitargeted DNA.

Limitations

- Ensure that there's not an obstruction, stricture or fistula where the little capsule would not be able to pass
- Recommended to avoid with cardiac pacemaker or implantable electro-medical device
- Patients with swallowing disorders- there would be concerns with choking because it is swallowing the capsule
- Contraindications or allergies to any medication or preparation agents

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- May not be performed not in conjunction with CT Colonography (CTC)

Optimally, if the **Val** has already prepped with a good prep, it would be administered at the time of the failed optical colonoscopy to avoid having to complete another preparation.

Note: CCE is not for screening, which is covered under NCD 210.3 and CCE is not a replacement for optical colonoscopy, but does allow an alternative in patients with the correct circumstances.

Magnetic Resonance Guided Focused Ultrasound Surgery System (MRgFUS) for the Treatment of Neurologic Conditions

This is an existing policy with the proposed changes to expand the coverage to include Tremor Dominant Parkinson disease. The changes are based on new literature in this population with an LCD reconsideration that shows the clinical benefit in this population.

The addition to the policy includes the expansion of this technology as reasonably necessary in patients with the following:

- Medication refractory (ONE)
- Essential Tremor ET)
- Tremor Dominant Parkinson's Disease (TDPD), with specified requirements to meet the diagnostic criteria.
    - » Refractory to Medical management and with a Scored Rating System on their Parkinson Disease Rating Scale
- Grading the severity of the tremor
- Disability of the tremor
- Patient is not a candidate for deep-brain stimulation

Limitations:

- Other contraindicated conditions
- History of bilateral thalamotomy
- Treatment of head or voice tremor
- Certain cognitive impairments
- MRI contraindicated
- Drug induced Parkinsonism
- History of seizures and brain tumors

MRgFUS is a promising new treatment that have attributes positive and negative distinct from traditional thalamotomy with limited coverage to expand this technology to the Parkinson associated Tremor. It is supported by the American Association of Neurological Surgeons, Congress of Neurological Surgeons, and the ASSFN.

MolDX: Minimal Residual Disease Testing for Cancer

Minimal Residual Disease Testing for Cancer is rapidly becoming a sensitive and specific method for monitoring the amount of tumor derived genetic material circulating in the blood of cancer patients. This policy is limited coverage to utilize this testing for diagnosis of cancer re-occurrence before there's clinical or radiographical evidence or help detect tumor response.

This will enable physicians to better stratify, help determine treatment options, or arm or adjuvant therapies.

Limited coverage allows for this testing:

- This policy does not supersede any of the conditions outlined an NCD 90.2
- The patient has a history of cancer and the type in staging is clarified
- The identification of recurrence or progression of the disease being the intended use of the testing.

The policy provides a quite a bit of specifics in terms of who would qualify for the testing and the requirements of the testing. The main point is that we want to utilize this to make sure that we're

using it to help monitor a therapeutic response or the early detection of re-occurrence outside of imaging or other traditional strategies.

Comments

All of the polices discussed are open to comment by November 22, 2020. Please send comments to CMD.INQUIRY@cgsadmin.com. We asked that you please include supporting literature wherever possible to best understand the evidence behind the recommendation.

Presenters

Dr. Ari Bergwerk is a pediatric gastroenterologist in clinical practice and also works part-time as salaried employee at Medtronic. Medtronic reviewed the Proposed Local Coverage Determinations for Colon Capsule Endoscopy. Medtronic appreciates the effort that went into the development of the policy and CGS recognition that PillCam qualifies for Medicare coverage.

This is diagnostic test that is safe and effective and reasonably necessary for defined a patient population.

The Proposed LCD indicates that CCE is not a Medicare benefit for colorectal cancer screening regardless of family history other risk factors for development of chronic disease.

Medtronic supports this limitation as PillCam COLON 2 is not FDA approved for colorectal cancer screening.

Medtronic respectably request that CGS moves forward with coverage for colon capsule endoscopy based upon FDA approved indications:

- It may be used for detection of colon polyps in patients after incomplete optical colonoscopy with adequate preparation, and a complete evaluation of the colon was not technically possible
- For the detection of colon polyps in patients with evidence of GI bleeding of lower GI origin. This applies only to patients with major risks for colonoscopy such as anesthesia or a moderate sedation, but could tolerate a colonoscopy with sedation in the event clinically significance abnormality was found at capsule endoscopy.

Closing Remarks

There were no questions.

Dr. Loveless thanked everyone for taking time to attend and Dr. Bergwerk for attending the open meeting.