



A CELERIAN GROUP COMPANY

J15 Open Draft/Revised LCD Meeting

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| Meeting Date and Time: | June 21, 2022, at 4:00 p.m. CST |
| Facilitator: | Dr. Meredith Loveless |
| Location: | Teleconference |

Dr. Loveless

Dr. Loveless briefly explained the polices to be reviewed during the open meeting.

Transcranial Magnetic Stimulation (TMS) is a proposed policy to expand coverage of TMS for indication of obsessive-compulsive disorder (OCD). The current policy is for the treatment of depression. CGS determined that this is investigational and did not meet the requirements of reasonable and medically necessary for the treatment for OCD. The indications for depression have not changed and will remain in the limited coverage.

Prostate Cancer Detection with IsoPSA™ is a limited coverage policy for testing for men aged 50 years and older prior to initial biopsy with a confirmed moderately elevated PSA. Additional literature has been published with clinical validity data and NCCN guidelines have been updated.

MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia is a non-coverage policy. The expectation for the test is defined in the policy. Currently, there are no test that demonstrated analytic and clinical validity to meet the necessary criteria.

MolDX: Prognostic and Predicative Molecular Classifiers for Bladder Cancer contains a revision to an existing LCD that has limited coverage for active bladder cancer

The policies are currently open for comment until July 3, 2022, for DL36469, DL39284, and DL39276. The comment period will end on 7/16/22 for DL38586. Comments are accepted through mail and fax, but the preferred submission method of the Draft LCD Comment Form can be sent to CMD.Inquiry@cgsadmin.com in PDF form for review.

- Draft LCD Comment Submission Form (A/B MAC Jurisdiction 15)
https://www.cgsmedicare.com/pdf/j15/j15_draft_lcd_comment_submission_form.pdf

Scott Blackman

Scott Blackman, Director of Market Access, reviewed OCD details and the review of the literature in the evidence for DL36469 - Transcranial Magnetic Stimulation (TMS).

- Request for CGS to decrease the number of failed trails based on the requirements of other Medicare Administrative Contractors (MACs) and commercial providers.
- Psychotherapy should not be a requirement
- 40-60% of patients fail to achieve a significant response from first line treatments
- Deep TMS™ OCD research confirms through published large evidence trails and protocol to support effectiveness, safety & durability with FDA Clearance



- Real-world evidence registry support that patience outcomes were significantly better than in the multicentral pivotal trail
- Long-term effectiveness and improvement in functional disability demonstrated durability of response and average of approximately two years after Deep TMS treatment
- Deep TMS is cost effective compared to the OCD treatments continuum

Bob Rochelle and Dr. Mark Stoovsky

Bob Rochelle, Chief Commercial Officer and Dr. Mark Stoovsky, Chief Medical Officer, from ClevelandDx presented for Prostate Cancer Detection with IsoPSA™.

- ClevelandDx suggests LCD Draft revisions to bring coverage in line with the recent peer-reviewed, prospective, multicenter study.
 - » According to Klein 2022 and other publications, IsoPSA™ is effective across a broad range of PSAs from 4-100ng/mL
 - » IsoPSA™ performs consistently in patients with prior negative biopsies and prior to initial biopsy
 - According to Klein 2022 and other publications, IsoPSA™ diagnostic performance of IsoPSA™ was consistent for primary and prior negative biopsy
 - Palmetto allowed both initial and prior negative biopsy for EXoDX and SelectMDx
 - » IsoPSA™ is useful in patients with symptomatic BPH taking 5-ARI and alpha blocker medications
 - According to Klein 2022, structural changes in cancer-related PSA are unaffected by drugs that lower PSA
- There are several minor typographical errors throughout the LCD
- Coding 89240 is a pathology procedure and is not appropriate
 - » Suggested unlisted MAAA code 81599 meets the requirements of CGS A58677
 - » 81599 would put IsoPSA™ in the same general category as 4K score 81359
 - IsoPSA™ evaluates patient risk of having HGPCa
 - IsoPSA™ evaluates multiple analytes, including PSA and free PSA, to derive a risk assessment through algorithm
 - 81599 is regularly paid by commercial payors

Closing

- Comments with supporting literature are greatly appreciated
- Comments and questions may be submitted to CMD.Inquiry@cgsadmin.com