

Jurisdiction 15

Open Draft/LCD Meeting

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Draft Local Coverage Determinations (LCDs)

Proposed Policies

- Transcranial Magnetic Stimulation (TMS) DL36469/DA57047
- Prostate Cancer Detection with IsoPSA™ DL39284/DA59066
- MoIDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia DL39276/DA59051
- MoIDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer DL38586/DA58065

Transcranial Magnetic Stimulation (TMS)

- This draft is in response to LCD reconsideration request to expand coverage of TMS for indication of Obsessive-Compulsive Disorder (OCD).
- Multi-MAC Contractor Advisory Committee Meeting was held 9/21/21.
- Literature review is summarized within the policy.
- CGS Administrators determines that the existing evidence and lack of accepted standards of medical practice for dTMS for OCD does not meet the requirement of medically reasonable and necessary, therefore coverage was not expanded to include OCD at this time.
- Coverage for depression was not changed in the proposed policy.

Prostate Cancer Detection with IsoPSA™

- Limited coverage policy for IsoPSA™ test
- Testing of men 50 years of age and older prior to an initial biopsy, who have a **confirmed*** moderately elevated PSA (greater than 4 and less than 10 ng/mL)

AND

No other relative contraindication for prostate biopsy including:

- Less than a 10-year life expectancy
- Benign disease not ruled out

*PSA elevation should be verified after a few weeks under standardized conditions (e.g., no ejaculation, manipulations, and urinary tract infections, no medications such as 5 α -reductase) in the same laboratory or other CLIA approved laboratory before considering a biopsy.

Prostate Cancer Detection with IsoPSA™

- CGS released a non-coverage LCD draft in October 2021. Since that time clinical validity data has been published and NCCN guidelines, have been updated to include IsoPSA™.
- New evidence addressed prior concerns regarding lack of clinical utility.
- Coverage criteria aligns with the study population.

MolDX: Molecular Testing for Detection of Upper Gastrointestinal Metaplasia, Dysplasia, and Neoplasia

- Non-coverage policy
- Expectations for a test to be covered are specified in policy.
- Although there are several promising molecular biomarker tests designed to further identify at-risk patients, there are currently no existing tests that have demonstrated analytical validity, clinical validity, and clinical utility to fulfill the necessary criteria.

MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer

- Revision to existing LCD
- Limited coverage policy
 - Active bladder cancer
 - One of the two criteria

The patient is a candidate for multiple potential treatments, which could be considered to have varied or increasing levels of intensity based on a consensus guideline, and the physician and patient must decide among these treatments. **OR**

The patient is a candidate for multiple therapies, and the test has shown that it predicts response to a specific therapy among accepted therapy options based on nationally recognized society consensus guideline.

MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer

- The test demonstrates analytical validity including both analytical and clinical validations
- If algorithm must be validated
- Test has demonstrated clinical validity and utility
- MolDX technology assessment

Open Comment Period

JURISDICTION 15 DRAFT LCD COMMENT SUBMISSION FORM

METHODS FOR SUBMISSION OF DRAFT LCD COMMENT FORM

Draft LCD Comment submissions may be sent via one of three methods: Email (preferred), fax, or hard copy by mail. Pertinent information is listed below for each of the three methods.

Type	Contact	Details
Email to (preferred method):	CMD.INQUIRY@cgsadmin.com	<ul style="list-style-type: none">• Electronic requests should be sent with "Draft LCD Comment Submission – [Name of LCD]" in the subject line.• If the attachment size for clinical citations exceeds 15 MB, the requestor must send the articles and supporting documents via multiple, smaller emails.• Please contact CMD.INQUIRY@cgsadmin.com for alternative methods for submitting large electronic files or if you have difficulty submitting a Draft LCD Comment form.
Fax to:	1.615.664.5971	Please address your fax cover sheet to: Draft LCD Comment Submission – [Name of Draft LCD] - Attn: Chief Medical Director
Mail to:	CGS Administrators, LLC Attn: Chief Medical Director J15 A/B MAC Draft LCD Comment 26 Century Blvd, STE ST610 Nashville, TN 37214-3685	N/A

Open Comment Period: Preferred Method

- Comment period for this policy ends on 7/3/22 (except DL38586 ends 7/16/22)
- To submit comments, go to:
https://www.cgsmedicare.com/pdf/j15/j15_draft_lcd_comment_submission_form.pdf
- Complete the PDF form and send attachments to
CMD.INQUIRY@cgsadmin.com
- Must provide supporting literature for the comments in full-text PDF
- Supporting literature must be published
 - In press and abstracts cannot be considered

Open Comment Period: Preferred Method

The comment link can be found on the CGS website under Medical Policies

Medical Policies

Coverage for services under Medicare is primarily established through the Social Security Act. Provisions of the Social Security Act are applied to specific services based on various regulations, National Coverage Determinations established by the Centers for Medicare & Medicaid Services (CMS), various CMS guidelines, and Local Coverage Determinations (LCDs) established by CGS.

- NCDs are developed by CMS to describe the circumstances for Medicare coverage nationwide for an item or service.
- LCDs are developed by Medicare Administrative Contractors (MACs), including CGS, and indicate whether a particular item or service is covered in accordance with the Social Security Act, section 1862(a)(1)(A). (See list of LCDs below.)
- NCDs and LCDs only address certain services and items; in other words, not every item or service has a corresponding NCD or LCD. In these cases, the Social Security Act, and in some cases, additional guidance published by CMS, establish the basis for coverage.
- For more information about NCDs, LCDs, and other coverage provisions, refer to the CMS Medicare Program Integrity Manual (Pub. 100-08), chapter 13 [PDF](#).
- [CAC Compliance Open and Provider Touch Point Meetings](#)
 - [CAC and Open LCD Discussion Recordings](#)
- [Top Provider Questions – Medical Affairs](#)
- [J15 Draft LCD Comment Submission Form PDF](#)

FEEDBACK

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Thank you for joining us!



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