

## Joint Jurisdiction 15 Open Draft LCD Meeting

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<b>Meeting Date:</b>	February 21, 2023
<b>Facilitator:</b>	Dr. Meredith Loveless, CMD
<b>Location:</b>	Teleconference

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

### DL39506-Cosmetic and Reconstructive Surgery

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Is a proposed LCD to provide clarification on the LCD coverage for cosmetic and reconstructive surgery.

#### Breast Surgery:

1. Breast reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is covered
2. Removal or revision of a breast implant whether placed for reconstructive or cosmetic reason, is considered medically necessary when it is removed for one of the following reasons:
  - a. Mechanical complication of breast prosthesis; including rupture or failed implant, and/or implant extrusion
  - b. Infection or inflammatory reaction due to a breast prosthesis; including infected breast implant, or rejection of breast implants
  - c. Other complication of internal breast implant; including siliconoma, granuloma, interference with diagnosis of breast cancer, and/or painful capsular contracture with disfigurement
3. Breast Reduction for symptomatic macromastia (breast hypertrophy)
4. Mastectomy for males with symptomatic gynecomastia Grade III and IV or abnormal breast development with redundancy, no underlying pathological causes or failed/refractory to treatment

#### Rhinoplasty:

Considered medically reasonable and necessary when the procedure is performed for correction and repair of any of the following indications:

1. Secondary to trauma, disease, congenital defect with nasal airway obstruction that has not resolved after previous septoplasty/turbinectomy or would not be expected to resolve with septoplasty/turbinectomy alone
2. Chronic, non-septal, nasal obstruction due to vestibular stenosis
3. Nasal deformity secondary to a cleft lip/palate or other congenital craniofacial deformity causing a functional impairment



### Septoplasty:

Considered medically necessary when performed for any of the following indications:

1. Septal deviation/deformity causing nasal airway obstruction that has proved unresponsive to a trial of conservative medical management lasting at least 6 weeks
2. Recurrent sinusitis secondary to a deviated septum that does not resolve after appropriate medical and antibiotic therapy
3. Asymptomatic septal deformity that prevents access to the other trans nasal areas when such access is required to perform medically necessary procedures
4. Performed in association with cleft lip or cleft palate repair
5. Obstructed nasal breathing due to septal deformity or deviation that is unresponsive to medical management and that medically necessary for CPAP treatment for obstructive sleep apnea.

### Chemical Peels:

Covered for the treatment of Actinic Keratosis

### Dermal injections:

For facial lipodystrophy syndrome in HIV positive beneficiaries using dermal fillers approved by the FDA for this purpose and in align with IOM requirements

### Abdominal Lipectomy/Panniculectomy:

Covered for the treatment of Actinic Keratosis

1. Abdominal Lipectomy/Panniculectomy is medically necessary when the pannus hangs below the level of the pubis, causes chronic intertrigo that consistently recurs and remained refractory to appropriate medical therapy over at least a three-month time period.
2. To alleviate complicating factors, such as inability to walk due to the pannus size pain, or intertrigo dermatitis.
3. Preoperative photographs may be required and kept on the file in case they are requested.
4. It is also considered medically necessary to a patient who has had significant weight loss following treatment for morbid obesity and has maintained stable weight for at least six months.
5. If the weight lost is the result of bariatric surgery should not be performed until at least 18 months after bariatric surgery and only when weight has been stable for at least 6 months and infection and inflammation has continued for the most recent 3 months.
6. It may be medically necessary if it is necessary in order to allow access for a primary surgery as if the pannus is thick, that adequate instrumentation to reach the site of dissection is necessary.

### Limitations:

Non-coverage includes:

- Any procedures performed for cosmetic purposes, including treatment of psychiatric or emotional problems
- Cosmetic procedure done at the time of a coverage service
- Any surgery to improve the appearance including liposuction, breast reconstruction, facial surgery without functional impairments
- Thyroid chondroplasty, rhinoplasty and rhytidectomy for improving appearance

### DL35986-Special Histochemical Stains and Immunohistochemical Stains

Existing policy based on new evidence and updated references.

#### Ki-67/MIB-1

- Exception to non-coverage for Ki-67 was defined for use as companion diagnostic to identify a high-risk population
- Updated role in neuroendocrine tumor detection
- Update to the DCIS section to align with 2020 ASCO/CAP Guidelines to allow marker when there are ambiguous histological morphological findings on H&E and the distinction between lobular and ductal differentiation

- Update to the Lynch Syndrome section to allow encases the screening for microsatellite instability
- IHC for predictive marker tumor profiling coverage is unchanged, but the list of specific tests was removed

### **DL34338-Transthoracic Echocardiography (TTE)**

Minor revision to existing policy and comments are only requested for the updated section.

- Added a section on CAMZYOS, which is a treatment for symptomatic obstructive hypertrophic cardiomyopathy at the NYHA Class II-III level
- Drug carries the risk of heart failure and requires close monitoring with TTE
- Use of additional TTE outside of the program

### **DL39521-Position emission tomography (PET) For Inflammation and Infection**

Noncoverage LCD for PET scan used in inflammation and infection is retired.

A CAC meeting was hosted a meeting in November of 2022 where subject matter experts reviewed pertinent literature and provided input for the development of the policy.

PET Scan will be considered reasonable and medically necessary for FUO when all the following conditions are met:

1. Fever is higher than one higher than 38.3 or 1 Celsius or 101-degree Fahrenheit
2. By definition of fever of unknown origin, it must be present for 21 days or greater with a fever occurring on two or more occasions when you're repeating episodes for two or more weeks prior to the study.
3. The patient is not immunocompromised investigation
4. Including history, physical laboratory, analysis, and standard imaging is non-diagnostic
5. The patient does not have any conditions that would limit the ability to interpret the PET

#### **Cardiac:**

PET scan is considered medically necessary when:

1. The clinical exam and laboratory evaluation lead to suspicion of the cardiac condition in question.
2. Non-specific or inconclusive imaging from echocardiogram and/or CT.
3. Cardiac pet scan preparation protocol is followed.
4. There are no conditions that would preclude the ability to interpret the pet scan.
5. If the study is for infective endocarditis, this would be applicable in prosthetic now.
  - i. Cardiac sarcoidosis, the patient has risk factors for cardiac sarcoidosis, such as systemic sarcoidosis, cardiac findings, a young patient with unexplained new onset conduction system disease, heart failure without explanation or
  - ii. The PET scan should be the primary test not used in conjunction with other cardiac imaging

If the patient is being evaluated for one of the following conditions and these specific criteria must be met:

- If there is a suspected infection of cardiovascular implanted electronic devices
  - i. Patient is unable to undergo an MRI because of the device
  - ii. Diagnosis is inconclusive on standard imaging
  - iii. Additional diagnostic studies would impact clinical care

#### **Limitations:**

- The need for PET scan and labeled WBC scan or PET scan and 67Ga SPECT/CT or PET scan and cardiac MRI as part of diagnostic evaluation is rare
- Individual consideration may be given on redetermination (appeal) for payment in rate, unique circumstances if the medical necessity of both studies and clearly documented in the medical records
- Frequent reporting of these services together may trigger focused medical review
- Endocarditis- PET scan is not reasonable and necessary for use in native valve
- PET and PET/CT is not a first line test and reserved for equivocal diagnostic cases

Use as a first-line study is not considered reasonable and necessary. The use of the pet scan for inflammation and infection of other conditions not specifically addressed is considered investigational.

Additional indications were explored and are listed within the LCD with a summary of evidence, but there was not sufficient evidence to support a role of this modality and therefore, consider not reasonable and necessary.

## Open Comment Period

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- Comments are accepted from 1/19/2023-03/05/2023
  - » Any feedback or suggestions, concerns from stakeholders, providers, beneficiaries within our community are accepted
- Preferred Submission Method
  - » Go to the following link and complete the PDF Form
    - Draft LCD Comment Submission Form (A/B MAC Jurisdiction 15):  
[https://www.cgsmedicare.com/pdf/j15/j15\\_draft\\_lcd\\_comment\\_submission\\_form.pdf](https://www.cgsmedicare.com/pdf/j15/j15_draft_lcd_comment_submission_form.pdf)
- Please provide supporting literature in full-text PDF
- Supporting literature must be published

## Presenters

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### Dr. Johnathan Myles

Dr. Myles offered a suggestion for Cosmetic and Reconstructive Surgery regarding specific coverage for the removal of the implant if the patient was to develop a lymphoma or another type of carcinoma is a complication of the implant. There were anecdotal reports that some private carriers review Medicare policies often to justify or not justify reimbursement.

The following statements are inconsistent with the some of the other statements in the policy.

- Dr. Myles agrees with the LCD language: Prostate cases that **may** require reasonable and necessary IHC staining include but are not limited to the following:
  - » In a multi-part biopsy with Gleason 3+3=6 cancer in 1 part, and atypical small acinar proliferation (ASAP) suspicious for Gleason 3+3=6 cancer in other part(s); the number of positive biopsy sites and % core involvement of these sites can affect therapeutic choices for active surveillance (AS), focal therapy or surgery.
  - » In a multi-part biopsy with 4+3=7 or 4+4=8 cancer in 1 part, and ASAP suspicious for the same grade cancer in other part(s); workup is justified since the extent of high-grade cancer affects treatments.
- Dr. Myles states that the following statements are incorrect and does not reflect medical practice. These two bullets are inconsistent with the information previously mentioned. The previous mentioned details states that looking at the number of course positive does provide additional actionable information.
  - » It is not reasonable and necessary to perform IHC testing in a negative or a suspicious core biopsy when obvious prostate cancer is present in other cores.
  - » While the pathologist may choose to confirm a suspicious focus in one or more cores in a case where the diagnosis of cancer has already been made, it is not a Medicare covered service because it provides no additional actionable information to the treating physician.
- The LCD Language: Prostate cases when IHC workup is Not Reasonable and Necessary include the following:
  - » In a multi-part biopsy with =3+4=7 cancer in 1 part, and ASAP suspicious for 3+3=6 cancer in other part(s), and stains are unlikely to change treatment,
    - There isn't a way to know the treatment options in advance because the patient doesn't even know that have a diagnosis of cancer yet,
    - 3+4=7 does not necessitate a radical prostatectomy,
      - > If the patient has a low percentage of Gleason Pattern 4, they are still a candidate for active surveillance,

- » 3+4=7 patients are still candidates for the focal therapy or partial prostatectomy,
  - > Knowing whether there is cancer in that other side of the prostate would influence therapy,

### Dr. Debra Zynger

Dr. Zynger stated that the following problematic statements:

- It is not reasonable and necessary to perform IHC testing (either single antibody or antibody cocktails) on cases with morphologically negative cores. It is not reasonable and necessary to perform IHC testing in a negative or a suspicious core biopsy when obvious prostate cancer is present in other cores.
  - » This precludes providers giving accurate information for risk stratification, and the risk stratification that is done based on the prostate biopsy determines management,
    - A few additional management options include: active surveillance, brachytherapy, external beam radiation therapy, external beam radiation therapy+ brachytherapy, external beam radiation therapy + brachytherapy + androgen deprivation, pre-treatment bone imaging, radical prostatectomy, radical prostatectomy + lymph node dissection.
    - Reasons to test other cores
      - > Each risk groups carry designated recommended therapies
      - > Laterality
      - > Prostate cases when IHC workup is Not Reasonable and Necessary include the following: In a multi-part biopsy with =3+4=7 cancer in 1 part, and ASAP suspicious for 3+3=6 cancer in other part(s), and stains are unlikely to change treatment.
  - » This statement is problematic because it doesn't allow the physician to stratify the patient per current guidelines.
- In a multi-part biopsy with =4+3=7 or 3+4=7 cancer in 1 part, and cribriform glands that include a differential of Intraductal Carcinoma of Prostate (ICD-P) "atypical cribriform lesion" (ACL) suspicious for intra-ductal carcinoma versus invasive, Gleason pattern 4 cancer in other part(s), because intra-ductal carcinoma is almost always closely associated with invasive high-grade cancer and the results will not change the overall highest Gleason grade/Grade group for the case and may not change treatment.
  - » Differentiate Gleason pattern four from introductory carcinoma
    - The recent score is used for risk stratification

### Closing

Written comments and suggested comments to support the comments in the form of published literature in PDF format were requested.

*Transcripts and recordings are available on the CGS website.*