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Jurisdiction 15 Open Draft Discussion

Meeting Date and Time:	July 13, 2021 at 2:00 p.m. CST
Facilitator:	Dr. Meredith Loveless, CMD
Location:	Teleconference

Dr. Loveless explained that polices that are proposed polices are discussed at the open meeting. Presenters sometimes shared additional information about the topic. The polices that are discussed today are open for comment and comments can be submitted to: CMD.INQUIRY@cgsadmin.com mailbox until August 7, 2021. We will respond to any comments, make changes in the policy, if appropriate or indicated, and then the polices will be finalized and become Local Coverage Determination (LCD) policies.

The polices discussed:

Epidural Procedures for Pain Management (DL39015)

The policy states that epidural steroid injections are considered medically reasonable and necessary when history, physical exam and radiological imaging study support the diagnosis of lumbar cervical or thoracic radiculopathy or neurogenic claudication, due to the images, which includes: central herniation, osteophyte, severe degenerative disc disease and central spinal stenosis, post-laminectomy syndrome, or acute herpes zoster pain.

The pain needs to be severe enough to cause significant degree of functional or vocational disability utilizing a pain scale, that pain scale not be measured at baseline assessment and then for follow-up assessment. Pain duration of four weeks or inability to tolerate noninvasive conservative care for any cases of acute zoster refractory to conservative management, where four-week wait would not be required.

Repeat steroid injections when the first injection provides at least 50% improvement in the lab per policy, utilizing the pain scale to measure the improvement, the injectant can contain corticosteroid anesthetic anti-inflammatory, the contrast agent, non-FDA approved agents would not be covered in the injected. The ESIs should be performed in conjunction with conservative treatment and the patients should be part of an active rehabilitation, home exercise or functional restoration program.

Limitations outlined in the policy, include, if not reasonable and necessary to perform multiple blocks during the session, as the epidural steroid injection except for facet synovial cyst.

The use of general anesthetic, moderate sedation, or Moderate Sedation and Monitored Anesthesia Care (MAC) is usually unnecessary, and if it was considered necessary, the medical record must document the reasons for that.

ESIs are not considered reasonable and necessary for treatment of non-specific low back pain, axial spine pain, complex regional pain syndrome, widespread diffuse pain, pain from neuropathy from other causes, or cervicogenic headache.

Dosing limits are outlined in the policy, no recommendation for the lowest effective amount, and it would not be considered reasonable and necessary for treatment to extend beyond 12 months. However, in cases that thought to be medically necessary, rationale for continuation,

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should be documented in the medical record, as well as communication with the primary care team.

Dr. Manchikanti's suggestions:

- Adhesiolysis is already deleted in two jurisdictions
- Rigid criteria are extremely rigid
  - With the present definition, only the eligible population may become 30% at the most 70%, but more likely 30% once you have 50% improvement
  - Three months majority of the patients will be eliminated.
- Overall leads to:
  - reduction in access
  - patient inconvenience
  - Increases the costs for patients, providers, and Medicare
  - Moving to expensive pigment
  - Increase this opioid utilization
  - Increases disability
  - Affects most significantly the vulnerable population: namely the elderly, disabled, poor and minorities

Dr. Solin's suggestions:

- Deletion of Percutaneous Adhesiolysis
  - Suggestion-Add to the LCD
- 12-month limit on ESI
  - Suggestion-Eliminate this portion of the LCD
- Duration between procedures
  - Suggestion-Still limit 4 per year, but consider more freedom to do them
- Cap on Total steroid dose
  - Suggestion-Change to lowest effective dose

Dr. Maus' suggestions:

Covered Indications #5 Repeat Injections

Suggest the following wording:

> ESIs are appropriate when 1 to 2 prior ESIs provided prolonged reduction in radicular pain 50% really for the condition being treated. ESIs should not be repeated within 14 days if a patient fails to respond well to a single ESI, or repeat ESI after 14 days can be performed using a different approach and/or oral medication, with the rationale and medical necessity for the second ESI documented in the medical record.

Covered Indications #6 ESI Injectant

The injections don't include steroid, they're not epidural "steroid" injections, so, we would so suggest replacing ESI injectant with the wording epidural injectant.

This will eliminate this confusing wording.

We would suggest the following wording: The epidural injectate must include contrast agent unless the patient has a contraindication to contrast. Injectate may also include corticosteroids, local anesthetic, saline, and or anti-inflammatories.

Covered Indications #7 Requirement of Other Conservative Treatment

Requiring other conservative treatment certainly were completely on board with this being a holistic treatment paradigm that some patients will benefit in, some patients will benefit from this multimodal therapy, but others will experience significant manner from the from the ESI alone. We suggest the rewording that ESIs may be performed in conjunction with conservative treatments rather than mandating.

Covered Indications New Indication-Diagnostic Spinal Nerve Block

Would also like there to be consideration to include diagnostic spinal blocks. Certainly in patients who did not respond well to an epidural steroid injections and then the practitioner must go and investigate if there are there other potential sources of pain which may occur from another signal level therefore, performing an additional diagnostic block is a critical investigatory tool.

Limitations

#1 Allow for ultrasound guidance in patients with this documented contraindication to contrast media for example, allergy or pregnancy.

#6 The limitation to four ESIs within 12 months neglects the circumstances where patients may have a relapse or development of an additional articular pain syndrome. So, we would suggest referring to a lowering three as an ESI for six months and six ESIs for 12 months, regardless of the number of levels involved.

#11 (Series of ESIs) There's absolutely no medical or scientific evidence that would support a series of three, but we do indeed wish that the practitioner would be allowed to repeat steroid injections based on the response to prior.

Suggested rewording as follows: It is not medically reasonable and necessary to prescribe a pre-determined series of ESIs and just leave it at that.

#12 (Steroid Dose) The dosages recommended are really an extrapolation of transforaminal doses to interlaminar injections. The interlaminar is almost certain that the local concentration of a corticosteroid is going to be lesser than a more targeted transforaminal approach and therefore, elevating the steroid, the dose to the lowest effective amount was slightly higher maximum doses so it would be more appropriate.

#13 (Treatment exceeding 12 months) Treatment exceeding 12 months is an unreasonable limitation. Many patients, particularly elderly population, the Medicare population of chronic stenosis and they will require ongoing treatment. These are lesions which are not going to go away, and in this radicular pain syndrome may be reactivated periodically and it's most appropriate to simply retrieve them rather than obligate they move on to surgery. We would suggest omitting this in requiring the pain physician to communicate the primary care provider to discuss whether the patient is eligible for this prolonged treatment is an unnecessary burden.

Provider Qualifications: We would strongly suggest replacing health care professionals with physicians. Physicians have the requisite training to select patients, safely perform technically demanding procedure, recognize, evaluate and potentially address any life altering complications.

This is very much in the scope of the practice of medicine. Absolutely. Next slide, please.

Society Guidance: North American Spine Society revised their coverage policy recommendations in 2020 and should be reviewed and replaced the 2013 and 2011 references. There are some typos regarding societies.

MolDX: Melanoma Risk Stratification Molecular Testing (DL38016)

It's a diagnostic test to assess the risk stratification for melanoma patients. It's a diagnostic test to assess the risk stratification for melanoma patients when all the following are true:

- The patient has a personal history of melanoma
- Either stage Tb1 or Tb1a with documented concern about adequacy of micro staging
- Undergoing evaluation for treatment
- Does not have metastatic disease
- Presumed risk for positive Sentinel Lymph Node Biopsy based on clinical histological or other information is greater than 5%
- Has a stage grade and Breslow thickness within the intended use of the test.

The test must demonstrate as part of the technical assessment demonstrating:

- Clinical validity
- Utility
- Appropriate analytical validity
- Performance characteristics equivalent or superior to other covered, similar tests

Dr. Prieto's suggestions:

The utility of gene expression profiling in melanoma can identify the true risk of sentinel lymph node metastasis. It can identify double negative patients whom we can confidently offer reassurance and surveillance by dermatology.

Identifies misclassify at AJCC low risk patients who are truly high risk for recurrence

Allows us to separate stage IIIA patients among a very heterogeneous group in and of themselves to better escalate or de-escalate management plans.

Ultimately, this sophisticated tool provides a previously unavailable data point that leads to actionable strategies, is precision oncology at its best, and I strongly recommend continued coverage for this invaluable test.

Dr. Rigel's suggestions:

We have results of the new articles that included the LCD, they should be interpreted with caution because they must be balanced out by the other hurdles.

There are significant methodological flaws of both the papers.

They limited their evaluation to full staging, rather, consider using this and stopping some of the unnecessary load biopsies.

There's significant additional evidence supported in the LCD publishes the last review two years ago.

The revision, because there are 10 times as many papers showing the positive effects of the task.

Patients with stage one melanomas, I mentioned, some will metastasizes die from the disease, but that subgroup are missed by today's staging practices. And they're identified through this test. At least higher subset.

There's extensive evidence that supports as close to the actual risk ratification value of this test. In combination with AJCC staging, especially the stage one patients where there significant in my view overuse of sentinel lymph node biopsy.

Dr. Goldberg's suggestion:

The data published today continue to support the validity and utility of decision DX Melanoma to identify patients with tumors 2mm in thickness or less who have a low risk of metastasis to the sentinel lymph node can safely forego the central to surgical procedure, and has previously determined after the recent reconsideration of the state and continue to meet the criteria for medical reasonableness and necessity.

We request consideration of research that evaluates decision DX melanoma test results in conjunction with a AJCC staging and other clinical pathologic features to improve the accuracy of risk prediction for patients with stage 1 through 3 melanomas. The Grossman and Marchetti articles recently added to the draft LCD, or the only authors' names specifically in the draft LCD text.

If these articles do not contribute additional tested patients to the published literature and have limitations that are not currently outlined in the draft LCD. Dr. Rigel spoke to some of those limitations and the Grossman article is an opinion statement informed by survey data with a low combined response rate of 14% of the surveys. In the Marchetti, all study does not make comparisons of the accuracy of GEP testing to the accuracy at AJCC staging alone or consider the improvement in prognostic accuracy provided by combining GEP with JACC staging approaches.

Castle Biosciences has submitted specific language for the proposed draft LCD modification during this open comment period and the points made in that submission are informed by the statements here on the slide just before the appended right here. There are formed by the statement seen here on this slide. At a high level we propose significant revisions to the draft LCD by including discussion of limitations of both articles recently added to the draft LCD, as well as discussion of the numerous studies published since the LCD went into effect that further support the prognostic accuracy and clinical utility. Of decision DX Melanoma to inform important clinical decisions in current practice.

MolDX: Next-Generation Sequencing Lab-Developed Tests for Inherited Cancer Syndromes (DL39017)

This policy states that all the following must be present for coverage eligibility:

- It needs to meet the criteria set in NCD 90.2 for coverage.
  - This would include any patient that has a cancer diagnosis
  - A clinical indication for germline, or inherited testing for hereditary cancer
  - A risk factor for germline inherited cancer
  - Has not been previously tested with the same germline test using next generation sequencing for the same germline genetic content.

The test must also have satisfactorily completed a technical assessment.

- Must include at least a minimum genetic content required for clinical decision making for the intended use.
  - Important to know that came from variance will change as the literature and drug indications evolve and therefore, they are listed separately and the associated documents., such as the MolDX TA forms.
  - A single gene may be tested if it is reasonable and necessary for the cancer type.
  - If a previous NGS test was performed with similar or duplicated intent, a subsequent catch would only be reasonable and necessary non genetic content on the second test.
- The test will not be covered if:
  - It does not fulfill the requirements and NCD 90.2 to
  - A previous test the same genetic content was performed.
  - It's used to identify unfamiliar variants that can be identified with a more specific test
  - It is used to confirm variant detected by somatic tumor testing that can be confirmed by more specific test
  - A satisfactory Technical Assessment is no completed
  - The technical assessment is not complete or for test that are currently covered by a TA submission has not been made, providers must submit completed material by the original effective date of the policy or coverage may be denied

Dr. Nussbaum's suggestions:

We believe that the guidelines that restrict germline testing for inherited cancer syndromes to patients meeting certain criteria, such as positive family history or early age at onset are insensitive and miss the majority of cancer patients who carry pathogenic variants in actionable inherited, a cancer syndrome genes.

We argued that these guidelines should be, should be dispensed with that universal germline testing for pathogenic or likely pathogenic variants in inherited cancer syndromes is clinically indicated for all cancer patients because of its value for management and treatment for a sizable fraction of these patients who would be missed if the guidelines were applied.

MolDX: Multiplex Nucleic Acid Amplification Test (NAAT) Panels for Infections Disease Testing

This policy has clinical indications for infectious disease testing for immunocompetent competent patients, when the clinical indication is the presumptive of active infection or infections associated with complications that require identification of causative organism for appropriate management.

A typical clinical presentation of a disease is considered appropriate for special populations, who may not present with classic symptoms of infection, which doesn't include the elderly.

For immunocompromised patients, a typical clinical presentation of disease is considered appropriate indications for testing.

The results of the testing will impact clinical management in a manner already demonstrated in the peer reviewed published literature and this includes performing the test for the intended sample type by the laboratory provision, the ordering physician to the major limitation of the given panel. An evaluation of more than one pathogen by NAAT testing is necessary for patient

management. Must include at least the minimum pathogens required for clinical decision making for the intended use that can be reasonable to detect the test.

Requirements of the policy are that the test demonstrate equivalent or superior test performance characteristics or analytical validity and clinical validity to establish standard of care method, and this must be specifically documented with documentation requirements outlined in the policy.

The panels will not be covered if the test is performed as a test of cure, if the patient has had a previous molecular diagnostic test for the pain pathogens within 14 days, if the previous panel is performed for similar duplicated intent. The exception would be repeat testing will be covered if the first panel has a negative result and there's a high index efficient for pathogen and the cognitive symptoms and the patient is not clinically improving.

Limited coverage for expanded greater than five pathogen panel tests requires respiratory and pneumonia panel, GI panel.

NP Broache's suggestion:

We ask that you add CPT code 81514 to the coding article as the codes 87481, 87661, 87801, which are currently included are no longer the most appropriate codes to bill for the BD Max Vaginal panel.

MolDX: Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (DL38997)

This is a limited coverage policy for prostate biomarkers diagnostic tests, to help differentiate men who may or may not benefit from prostate biopsy when all the following conditions are met:

1. The eligible patient for this test is a candidate for prostate biopsy or repeat prostate biopsy according to the NCCN guidelines.
    - » For men less than 75 prostate specific antigen or repeat prostate specific antigen greater than three and less than 10, or end or rectal exam findings that are suspicious for cancer, and
    - » For men over 75, PSA range greater than four and less than 10 or clinical exam findings.
2. The patient has not had a prostate biopsy or how to create negative or nonmalignant but abnormal histopathology finding.
    - » Patients under consideration for repeat biopsy, they have undergone the first repeat PSA or rectal exam testing and repeat biopsy is considered within 24 months of the previous biopsy.
3. The patient must benefit from treatment for the prostate cancer.
4. The beneficiary is within the population, which is developed and validated.
5. If the test relies on an algorithm, the algorithm must be validated, in a cohort that is not a developmental cohort for that algorithm.
6. The test must meet clinical validity, and clinical utility, and peer reviewed published literature establishing clear insignificant biological molecular basis for stratification and selection.
7. The test is ordered by a physician specializing in the management of prostate cancer, or urologist, or an oncologist.

Dr. Kader's suggestion:

- PSA based prostate cancer biopsy decisions have saved lives, but it's substantial financial and human cost.
- Polygenic genetic risk scores, together with other biomarkers will play an important role in making both initial and repeat biopsy decisions, which really need to be better defined.

Electroretinography (DL38992)

CGS did not have any presenters for this policy, but Dr. Loveless provided a brief review of the draft.

- Electroretinography is considered reasonable and necessary for the following:
- Detection of loss of retinal function
- To distinguish retinol from optic nerve lesions
- Detection of chloroquine and hydroxychloroquine toxicity
- ERG is considered investigational for all other indications, including glaucoma
- Toxic retinopathies can be caused by intraocular metallic foreign bodies and certain drugs
- Diabetic retinopathy
- retinal vascular diseases
- Autoimmune retinopathy

Electroretinography was supported by evidenced in the medical literature and therefore covered.

ERG for glaucoma was a subject of debate. We concluded that it is not recommended. This aligns with the AAO guidelines, as it is not t included in any of the guidelines for US or other country guidelines. The measurements for ERG glaucoma have been established, the clinical practice and utility are still investigational.

Platelet Rich Plasma Injections for Non-Wound Injections (DL39023)

CGS did not have any presenters for this policy, but Dr. Loveless provided a brief review of the draft. This is a non-coverage policy for the use of platelet rich plasma injection an application for the management of musculoskeletal injuries and joint condition.

This policy is non coverage and does include the list of conditions provided that includes treatment of tendinopathies, epicondylitis, carpal tunnel, rotator cuff plantar fasciitis, patellar tendinopathy surgical management, osteoarthritis, back pain, dental and oral surgery.

The policy does review the evidence that is currently available for each of these, and, in the rationale of the policy, explain the reasoning behind the non-coverage decision, which is that these products lack standard processing, treatments and protocol that that would be required to meet the reasonable and necessary requirements.

Closing

We appreciate all our presenter's time and providing education for us and we will consider the presentations and submitted comments.

Comments are due by August 7th, 2021

After the written comment period has closed, we will move the revise and make any necessary revisions draft will be finalized and there will be a response to comment article published with the final draft. That article is important because it explains the reason behind all decisions made between this draft policy and final policy.