Jurisdiction 15 Open Draft LCD Meeting

Meeting Date & Time:	October 30, 2024
Facilitator:	Dr. Meredith Loveless
Location:	OSU Wexner Medical Center

Dr. Loveless advised that the structure of future meetings for Compliance and Provider Touch Point will be held virtually. Open meetings will be virtual with the exception of one open meeting per year for J15 with a rotation between Kentucky and Ohio.

Dr. Loveless introduced the Proposed polices to be discussed and informed everyone that the comment period is currently open for all polices.

DL39938/DA59860 MolDX: Genetic Testing for Heritable Thoracic Aortic Disease

- Covered when the patient has aortic root or sending aortic dilatation aneurysm or dissection (as defined by the national consensus guidelines)
  - Presenting prior to the age of 60 OR
  - Presence of syndromic features of Marfan syndrome, Loeys-Dietz syndrome, or vascular Ehlers-Danlos syndrome,
  - The patient has symptoms of one of the conditions related to this family history of thoracic aortic disease or intracranial aneurysm in a first- or second-degree relative OR
  - A family history of unexplained death at a young age in a first or second degree relative.
  - It requires that the patient has received appropriate genetic counseling, and the testing is selected to include the minimum genetic content that will help to establish the diagnosis and aligns with current guidelines.
  - A single variant test would only be appropriate if that's a known familial variant.
  - The test does not include additional genetic content that can be considered harmful to the patient or conflict with any other policies
  - Meets the MolDX requirement for a technical assessment.

DL4000/DA59919 MolDX: Non-Next Generation Sequencing Test for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms

- This policy will cover multi-gene no-next generation sequencing panel for testing for the workup of BCR-ABL negative myeloproliferative neoplasms (MPN)s
  - Limited to classical neoplasia
  - Myelodysplastic and myeloproliferative neoplasms are considered a separate class and out of the scope of this policy and addressed in a separate policy.

Criteria:

- Patient is being evaluated for one of these conditions, aligning with the international consensus diagnostic criteria for them
- This test would be helpful in being able to diagnose and appropriately treat the patient targeting the genes that that may help to identify a genetic condition and have an impact on treatment management.
- The test goes into more specifics about the use of single gene test and reflex testing clarifying that negative test results would then progress to criteria number to criteria three and four as outlined within the policy.

- The test must meet all of the requirements as usual for the molecular diagnostics, including that the panel must include the minimum necessary genes that the documentation must be consistent, clinical validity must be established for the test being used in the appropriate populations.
- The test does complete the technical assessment as required by MolDX
- Test of similar methodology will each be considered for coverage as part of the Moldx program
- Not be utilized as a test of cure

DL39940/DA59862 Molecular Testing for Identification and Management of Hereditary Transthyretin Amyloidosis

- The patient would have to have a clinical diagnosis
- Cardiac features suggestive of ATTR cardiomyopathy,
- African American descent or first degree relative with the condition
- Has at least one additional feature suggestive of the condition, based on expert consensus and society guidelines.
- Patient has been offered counseling
- The test will help in determining treatment and include the minimum genetic content necessary to aid in the diagnosis without genetic content that could be considered harmful.
- Single variant testing if reasonable and necessary, in which case it would be a known familial variant and having completed the appropriate technical assessment.

DL39958/DA59880 Intervertebral Disc Injections (Via Disc) 0627T

- This is a non-coverage policy for injections for intravertebral disc repair.
- This is based on insufficient evidence of efficacy and improved outcomes from the current literature for the treatment of low back pain.
- This is reviewed in the policy of the literature that was reviewed and the rationale for why that the evidence fell short of coverage.
- CPT codes: 0627T, 0628T, and 0628T, and 630T are non-covered

DL34045/DA56697 Non-invasive Vascular Studies

- LCD reconsideration in which there was a request to expand coverage.
- Requesters provided the evidence to support expansion, and therefore the policy has been expanded accordingly and the code has been added to the article.

Dr. Loveless

Dr. Loveless let those in attendance know that they can submit comments by completing the Dreft LCD Comment Submission form and email by November 23, 2024.

The preferred method of comment submission is CMD.INQUIRY@cgsadmin.com

- Comments can be fax or mailed
- PDF form to submit comments is available on CGS's website
  - » https://www.cgsmedicare.com/pdf/j15/j15_draft_lcd_comment_submission_form.pdf
- Literature must include peer reviewed and published support literature

Reminder: Informal meetings are preliminary discussions related to guidance on the process of LCD request or reconsideration.

Presenters:

Dr. Doug Beall (Speaker)

LCD Concerns:

- Discogenic back pain just received an ICD-10 code recently
  - » Contains the largest portion of people that suffer from back pain
- To track utilization is somewhat of an issue because there are nine commingled items

The most common cause of back pain in the United States, and specifically this is a

perspective multicenter single ARM control trial.

Evaluating low back pain from L1 to S1 in people with degenerative disc disease.

This is a perspective multi center single ARM control trial evaluating the injection of nucleus pulposis allograft for back pain in the lumbar spine.

The Inclusion includes:

- People that have had six months or more of back pain and no radicular symptoms to speak of.
- This is for moderate or moderate to severe lumbar degenerative disk disease and with an Oswestry score more than 40, which is moderately disabled in a numerical rating score of more than six on a scale of 0-10.

The Exclusion includes:

- Anybody that does not experience discogenic back pain

The primary endpoints are function and safety. The secondary endpoints are pain, function, disc health.

- There was a significant decrease one month and this is more than 45%. It gets down to 58% of relief for more than four points, which is a good benchmark in the numerical rating scale. We're looking for a four point or more reduction of pain by 6 months and that holds true all the way out through two years.

Dr. Beall provided a score to support a 47% reduction of one month of a micronized allograft without anesthetic. By 6 months there was a 30 point reduction in Oswestry, which is a category and 1/2.

A very significant reduction that continues all the way out through 24 months.

- Importantly, Dr. Beall mentioned that responder rates are reviewed. In terms of pain responders, 30 or 50% and in both of these categories, we have 2/3 of the patients are responding at more than 30 and then more than 50% responder rate.
- Functional responders
    - » There are 15 and 30 as Oswestry points
    - » Almost a category and then a category and a half
    - » There was a 75% response rate for people responding to improvements in function as measured by ODI
- Safety Profile
    - » Safety is one of the important things that had one persistent SAE at six
    - » No other significant adverse events persisted.
    - » One of the persistent one was radiculopathy, which this is not a product to treat radiculopathy or sciatica, but this nevertheless later resolved
- Conclusion
    - » Fairly profound relief
    - » The percentage of reduction that started at month one, it maximizes by month six and last all the way out through 24 months of 58-57% improvement in pain and function respectively.
    - » Responder rates almost 2/3 responded in terms of pain at the highest level of greater than 50% pain reduction and then.
    - » Almost 3/4 responded the highest level, which is more than 30% improvement in function is measured by Oswestry
    - » The pain and functional benefits started early and maintained itself at one year and two years with very positive safety profile.

Dr. Beall confirmed that this documentation is press recently accepted. We have confirmation of acceptance. It is impress an accepted publication. This was a perspective multicenter single ARM control trial.

Dr. Shrif Costandi (Speaker)

Disc joint pain is a is a common and prevalent condition that is encountered all the time. The challenge with that subset of patient population is that a lot of them are from the younger patient population. It has a direct impact on the working force and really has its own indirect

impact on the economy overall as well.

With the new proposed LCD, Dr. Costandi believes that it will limit all the options that are available to our and that will lead to possibly increase medical management.

- which typically entails opioid management
- Surgical interventions, which do not really have great outcomes with patients, with discogenic pain

The new proposed LCD has really bundled failed attempts of trying to treat patients.

Dr. Costandi was the principal investigator in the Cleveland Clinic and his patients that had substantial pain improvement and not just in pain scores, but also in their daily function and their functionality.

Dr. Costandi has some data and literature that has been accepted and in the process of being published.

In conclusion, this will again limit the access of a of a young, challenging patient population and will lead to more opioid utilization and some more certification adventures, which are typically higher cost and with without positive outcomes.

Dr. Loveless

Mentioned the article, “Principles of Study Design” listed on the CGS website is helpful in explaining how we review evidence for coverage decision within Medicare. The evidence should demonstrate that the intervention in question in change or progress that is made is due to the intervention and not chance.

Studies that place controls and reduce bias and measures like that are going to be the most successful in in providing confidence.

Evidence is evaluated purely to answer those questions, and it's not evaluated for cost effectiveness within the Medicare program.

The standard for being able to know if something is due to the intervention can impact that might be the risk of bias.

- Different biases that are introduced within it.
    - » The sample size, how long something is of Is looked at over time
    - » The randomization can impact is a source of bias

All those details are evaluated and then that's analyzed and explained in located into the LCD under the evidence and then the rationale for decision, how we've come to the decision that's made is explained in the rationale for decision section.

We consider real world evidence. Real world evidence is evidence that's collected outside of the rigorous study design, such as, you know, a controlled study. It might be that it's collected from databases, electronic records, so sources.

That are that are outside of formal study design. These are difficult to utilize to answer that question.

There's so many potential biases and things that may make it difficult to draw to be confident in that that conclusion. It can be valuable to help define populations to look at populations that may have been excluded in a more rigorous study design, so can help address healthcare disparities. For instance, in Medicare studies often exclude patients in the Medicare age range.

So sometimes that real world data may help us to understand how something impacts a Medicare age range. For instance, we had a policy on the waterjet for prostate and that study when it was done was well done randomized control trial and the policy that came out aligned with the study design because that's what we knew that this works in subsequently.

It was utilized in people older than the initial population. They turned in that real world data and through an LCD reconsideration process that age limit was removed from the policy.

The final section of the LCD, there's a definite role for real world data, which is data that's collected not within the robust design of a clinical trial but collected from patient registries, electronic medical records and sources like that look at a population that received an intervention. It does have limitations in being able to provide confidence in an intervention because it's not designed to control for all these potential things that could affect the ability to know if this if there is a chance or not.

Dr. Loveless closed the call by inviting everyone to CGS website to view the 2025 meeting schedule.