Jurisdiction 15 Open Draft LCD Meeting

Meeting Date & Time:	November 8, 2023
Facilitator:	Dr. Meredith Loveless, CMD
Location:	Marshall Women's Health and Education Center/Teleconference

Dr. Loveless briefly introduced the Proposed Polices that are to be discussed:

DL39656/DA59480 Trigger Point Injections

Trigger point injections that are used in pain management and these will be considered reasonably and medically necessary to treat myofascial pain caused by trigger points when the following requirements are met:

1. There is a focal area of pain in the skeletal muscle.
2. There is clinical evidence of a trigger point defined as pain in a skeletal muscle that is associated with at least 2 of the following findings: the presence of a hyperirritable spot and/or taut band identified by palpation and possible referred pain, AND
3. The physical examination identifies a focal hypersensitive bundle or nodule of muscle fiber harder than normal consistency with or without a local twitch response and referred pain, AND
4. Non-invasive conservative therapy is not successful as first line treatment OR movement of a joint or limb is limited or blocked OR the TPI is necessary for diagnostic confirmation.

Subsequent TPI

Repeat Trigger point injections in previously injected trigger points will be considered medically reasonable and necessary to treat myofascial pain syndrome when all the following requirements are met:

1. There is a positive pain response from the most recent TPI defined as providing consistent minimum of 50% relief of primary (index) pain after the TPI measured by the SAME pain scale* at baseline and post-injection, AND
2. Consistent pain relief from the most recent previous TPI lasting at least 6 weeks1 AND
3. The myofascial pain has reoccurred and is causing objective functional limitations measured by a functional scale obtained at baseline and after TPI which demonstrated at least 50% improvement from the previous TPI.

Requirements

1. Patients should be part of an ongoing conservative treatment program and documentation to support the patient is actively participating in a rehabilitation program, home exercise program or functional restoration program is in the medical record.
2. There should be at least 6 weeks duration before TPI is repeated in the same location.
3. Trigger point primary index pain must be measured prior to the injection at the beginning

of the session.

4. The post procedure pain level must be measured after the TPI at the conclusion of the session using the same scale* utilized at baseline.
5. When documenting the percentage of pain relief from the primary (index) pain compared to the post-injection pain levels, it is insufficient to report only a percentage of pain relief and/or a nonspecific statement of the duration of pain relief. The documentation should include a specific assessment of the duration of relief being consistent or inconsistent with the agent used for the injection and the specific dates the measurements were obtained using the SAME pain scale* used at baseline.
6. When documenting the ability to perform previously painful movements and activities of daily living (ADLs) it is insufficient to provide a vague or nonspecific statement regarding the improvement of previously painful movements and activities of daily living (ADLs). The documentation should include a functional assessment to show clinically meaningful improvement with painful movements and ADLs, if this metric is used to justify the efficacy of the TPI Providers should use established and measurable goals and objective scales to assess functionality and ADLs measures.

Limitations

- No more than three (3) TPI sessions will be reimbursed per rolling 12 months.
- A TPI involves the use of a local anesthetic and does not include injections of biologics (e.g., platelet rich plasma, stem cells, amniotic fluid, etc.) and/or any other injectates.
- It is not considered medically reasonable and necessary to perform TPI into multiple muscle groups in different anatomical regions during the same session.
- It is not considered medically reasonable and necessary to perform multiple blocks (ESI, sympathetic blocks, facet blocks etc.) during the same session as TPI.
- Trigger points injections for treatment of headache, neck pain or low back pain in absence of actual trigger points, diffuse muscle pain, a chronic pain syndrome, lumbosacral canal stenosis, fibromyalgia, non-malignant multifocal musculoskeletal pain, complex regional pain syndrome, sexual dysfunction/ pelvic pain, whiplash, neuropathic pain, and hemiplegic shoulder pain are considered investigational and therefore are not considered medically reasonable and necessary.
- Use of fluoroscopy or MRI guidance for performance of TPI is not considered reasonable and necessary.
- The use of ultrasound guidance for the performance of TPI is considered investigational.
- Trigger point injections used on a routine basis, e.g., on a regular periodic and continuous basis, for patients with chronic non-malignant pain syndromes are not considered medically necessary.

Indications

- TPI are covered for refractory pain associated with trigger points that do not respond to conservative therapy or in patients with significant limitations in mobility that can be improved by the trigger point while undergoing conservative treatment.
- A single diagnostic trigger point can play a role in diagnosis for myofascial pain and Abdominal Cutaneous Nerve Entrapment Syndrome (ACNES).
- There is evidence to support a role for treatment of headache if associated with the presence of a trigger point.

DL38662/DA58127 Implantable Continuous Glucose Monitors (I-CGM)

The LCD has been updated based on new evidence to expand coverage which aligns with current guidelines and also DME updated policy.

DME covers the device and supplies and Part A/B covers the insertion of the implantable device

- The requirement for insulin three or more times per day, and frequent adjustments based on blood sugar has been removed.
- The policy now allows for beneficiaries treated with insulin with sufficient training on I-CGM use.
- The policy expands to allow for those with documented repeated hypoglycemia events.

1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's

caregiver) has sufficient training using the I-CGM prescribed as evidenced by providing a prescription; and,

3. The I-CGM is prescribed in accordance with its FDA indications for use; and,
4. The beneficiary for whom a I- CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:
    - » The beneficiary is insulin-treated; or,
    - » The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following:
        - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
        - A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.

Requirements

Every six (6) months following the initial prescription of the I-CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their I-CGM regimen and diabetes treatment plan.

DL39648/DA59472: MolDX: Gene Expression Profile Tests for Decision-Making in Castration Resistant and Metastatic Prostate Cancers

Used to assess the risk or predict therapeutic response in men who have established diagnosis of castration resistant or metastatic prostate cancer.

- Help guide treatment decisions in men with prostate cancer
- It is to be applied to beneficiaries whose life expectancy is such that there's ongoing treatment for the cancer and there is multiple treatment options to consider that the test might guide

Coverage Criteria

- The patient has not been tested with the same or similar test for prostate cancer.
- The patient has not received pelvic radiation or androgen deprivation therapy (ADT) prior to the biopsy or prostate resection specimen on which the test will be performed.
- Commercial test must demonstrates analytical validity (AV), clinical validity (CV) and clinical utility (CU)
- If it requires an algorithm that must also be validated, it also must meet the laboratory improvement amendments and FDA regulations.

Decipher GC is a cover test under this policy and expanded based on evidence to support it. It is limited to one test per patient.

DL39650/DA59474: MolDX: Molecular Testing for Risk Stratification of Thyroid Nodules

- This is a limited coverage policy and applies to beneficiaries with indeterminate or suspicious thyroid nodules.
- It requires that the patient has not been tested with the same or similar test previously that the nodule is in determinant category three or four, or category 5 where the testing has been determined that it would be beneficial for stratifying the type of malignancy.
- It must be used in the aid of surgical decision making after consideration of the clinical radiographic inside cytological features.
- Must meet all of the validity and utility criteria to be covered to complete the technical assessment, have published evidence to support the population for which it applies, and for any new tests that are at least as good or potentially better than the existing test.
- NCCN guidelines emphasizes that this needs to be used in the total care of the patient, but consider all of the factors that may impact the patient’s treatment and decision making.

DL39658/DA59482: MolDX: Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy

This a limited coverage.

The test can be used for diagnosis or exclusion of lung cancer with an indeterminate pulmonary

nodule when a bronchoscopy is non-diagnostic when conditions are met:

1. The beneficiary has undergone bronchoscopy for an indeterminate pulmonary nodule
    a. The bronchoscopy has failed to provide a specific histopathological diagnosis such that further diagnostic procedures are considered necessary to pursue a specific diagnosis (non-diagnostic bronchoscopy); AND
    b. Test results will be used to meaningfully inform patient management within the framework of nationally recognized consensus guidelines.
    c. If medically reasonable and necessary following established guidelines, the nodule cannot be evaluated by an alternate methodology (EBUS, FNA, etc.) for a specific diagnosis.
2. The beneficiary does NOT have any of the following:
    a. Personal history of cancer
    b. Current diagnosis of cancer or high clinical suspicion for cancer
    c. An overall low risk for pulmonary malignancy such that test results would not meaningfully alter patient management and significantly improve patient outcomes.
    d. An overall high risk for pulmonary malignancy such that test results would not meaningfully alter patient management and significantly improve patient outcomes.
3. The beneficiary has not been tested with the same or similar assay for the same clinical indication.
4. The beneficiary is within the population and has the indication for which the test was developed and is covered. The lab providing the test is responsible for clearly indicating to treating clinicians the population and indication for test use.
5. The test has demonstrated clinical validity and utility, establishing a clear and significant biological/molecular basis for stratifying patients and subsequently selecting (either positively or negatively) a clinical management decision in a clearly defined population.
6. Clinical validity of any analytes (or expression profiles) measured must be established through a study published in the peer-reviewed literature for the intended use of the test in the intended population.
7. Rule-out tests should have a high sensitivity and negative predictive value (NPV) such that patients can be safely selected for a less aggressive management strategy without delay to diagnosis due to false negative results.
8. Rule-in tests should have a high specificity and positive predictive value (PPV) such that patients can be safely selected for more aggressive management without significantly increasing procedures in patients without cancer due to false positive results.
9. The test demonstrates analytical validity including both analytical and clinical validations. If the test relies on an algorithm (which may range in complexity from a threshold determination of a single numeric value to a complex mathematical or computational function), the algorithm must be validated in a cohort that is not a development cohort for the algorithm.
10. Tests utilizing a similar methodology or evaluating a similar molecular analyte to a test for which there is a generally accepted testing standard or for which existing coverage exists must demonstrate equivalent or superior test performance (i.e., sensitivity and/or specificity) when used for the same indication in the same intended-use population. New tests that become available with significantly improved performance may render older tests no longer compliant with this policy.
11. The test successfully completes a Molecular Diagnostic Services Program (MolDX®) technical assessment that ensures the test is reasonable and necessary as described above

- Guidelines on the management of intermediate risk patients with IPNs show heterogeneous recommendations. Moreover, management options in these patients include bronchoscopy, an invasive procedure with an overall diagnostic yield of 69% according to a recent study. Therefore, whenever possible, IPNs in these patients should be investigated using noninvasive procedures in order to avoid morbidity in patients without cancer. Molecular biomarkers can fulfill this need.
- The evidence published to date has demonstrated clinical utility and validity of molecular biomarkers as high sensitivity “rule-out” tests for current or former smokers with indeterminate pulmonary nodules and intermediate risk of malignancy who have undergone a non-diagnostic bronchoscopy. These tests can effectively re-classify risk

of malignancy from pre-test “intermediate” to post-test “low” risk in patients with a non-diagnostic bronchoscopy and negative classifier result. This re-classification can inform the management of post-test low-risk patients and impact management.

- The ability of these test to rule-in malignancy is not as clear. The benefit of testing patients with a low pre-test risk of malignancy for whom CT surveillance is the recommended follow-up strategy according to practice guidelines is also unclear, as re-stratification to a very low risk category leads to the same recommended intervention (i.e. CT surveillance).
- Decision-making in patients with IPNs is complex, and a given molecular biomarker offers a single data point to be considered within the broader clinical context. Additional factors such as surgical risk, patient preference, resource availability and physician experience also play a role in IPN management.

DL38582/DA58061: MolDX: Molecular Testing for Solid Organ Allograft Rejection

This is a limited coverage policy for molecular diagnostic test for management of patients who have undergone solid organ transplantation and so this test is utilized to assess the transplanted allograft for rejection status.

Molecular diagnostic tests that assess a transplanted allograft for rejection status are covered when ALL of the following criteria are met:

- The test must provide information about at least one of the two following clinical status determinations:
  - AR status
  - Cellular or Antibody-mediated rejection (ACR or AMR) status
- Must play a clinical role in decision making
  - May alter the patients treatment plan by changing their immunosuppression
  - This test may prevent them from having to go through a biopsy if they're able to gain the information they need to confirm that the patient is no rejecting
  - May confirm that additional management is needed
- No molecular diagnostic test or covered if it not going to inform clinical decision making that applies to this test.

Dr. Francine Kaufman presented for Implantable Continuous Glucose Monitors (I-CGM)

Senseonics is the manufacture of the only implantable CGM device that is available in the U.S. market. There is a sensor available, Eversense E3-CGM, that lasts 180 days. It is a fully implanted sensor that is performed as an in-office procedure.

There is a transmitter that gets raw data from the sensor, converts it into a glucose value that's shown on this smartphone application or app, and the glucose value changes every five minutes and elicited both on the arm and the transmitter, as well as on the smartphone are alerts for high and low glucose values.

It is a fully implanted sensor inserted and removed by trained and certified health care providers. This is under a payment system in which the device and the physician fee is bundled together. It's a replacement for finger sticks, and we're indicated only for adults and was approved by the FDA in February of 2022.

The LCD is supported with removal of the requirement that the beneficiary be treated with insulin through three or more daily administrations or with a continuous subcutaneous insulin infusion pump, and to add the history of problematic hypoglycemia.

This updated criteria for coverage of implantable CGM reflects the current clinical evidence, and the standards for reasonable and necessary use of CGM.

There is a robust body of evidence in the medical literature supporting this position. There are several important randomized controlled trials that show the benefit of using CGM and Type 2 diabetes. Patients who use basal insulin or only one insulin injection per day rather than multiple daily administrations of insulin, or use of an insulin pump. There are three systematic reviews with meta-analysis that showed CGM use in patients with type 2 diabetes compared to finger stick. Measurements of glucose was associated with significant reduction in hemoglobin A1C levels. The ultimate marker of diabetes adherence and control, and there are two prospective clinical trials showed that the clinical significant episodes of hypoglycemia go undetected without CGM and Type 2 patients either using insulin or being treated with non-insulin regimens. The major professional Diabetes Associations in the United States have made favorable

Closing Comments

- Senseonics supports Draft LCD DL38662.
- The changes in coverage are in concert with the medical literature and positions of the major Diabetes Associations.
- The updated coverage criteria provides parity for coverage across all CGM systems, including the DME as well as the implantable categories.
- Request that CGS Add all relevant ICD 10 diagnoses to DA58127.
- Initial submission includes a list of 81-ICD-10 diagnosis codes that are not currently listed

Dr. Loveless

Confirmed that the comment period is open until November 18, 2023.

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
- Comments 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.