Meeting Name: Jurisdiction 15 Open Draft LCD Meeting
Meeting Date and Time: October 25 and 26, 2022
Facilitator: Dr. Meredith Loveless
Location: Teleconference, Norton Women's & Children's Hospital, and Ohio State University Wexner Medical Center, and update

Dr. Loveless briefly explained the single polices to be reviewed during the open meeting.

Sacroiliac Joint injections and Procedures DL36029/DA59154

- Proposed draft that is part of a multi-MAC collaborative
- Sacroiliac joint is uniquely challenging as it is a complex structure, and the exact pattern of innervation is unclear. Pain from the SIJ join can be significant and severe.
- The literature related to sacroiliac joint pain is limited by few placebo-controlled trails, lack of long-term data, inconsistencies in diagnostic criteria, assessment of outcomes, and techniques of the procedure.
- This results in a great deal of heterogeneity between studies

- Sacroiliac Joint Injections is considered medical reasonably and necessary
  - When there is moderate to severe low back pain of the SI joints
  - Low back pain duration of at least three months
  - Low back pain below L5 without radiculopathy
  - Clinical findings do not suggest any other diagnosed or obvious cause of the lumbosacral
  - Three positive finds with provocative maneuvers
  - Four weeks of conservative therapy without success.
- Diagnostic of Sacroiliac Joint Pain
  - Injections are typically used to help determine if it is SIJI
  - Diagnostic injections performed under CT or fluoroscopy image guidance
  - Not to be performed with other musculoskeletal injections in the spine
  - An improvement of 75% pain relief after the diagnostic injections, measured by the same pain scale used at baseline
  - KX modifier is required
  - After the initial diagnostic injections, additional diagnostic injections to be necessary
- Therapeutic Sacroiliac Joint Injections
  - Continuation and improvement of pain between the injections, of at least 50% pain relief or 50% improvement and function
  - No more than four therapeutic injections will be considered reasonable unnecessary in a rolling 12 months
- SIJ Denervation
  - Considered investigational and not reasonable and necessary
- Requirements
  - Should be performed with conservative therapy.
  - Part of an actively participate actively participating in a rehabilitation program may be performed general unilaterally or bilaterally.

Dr. Byron Schneider, Vanderbilt University Medical Center

- SIG denervation is considered investigational and therefore, not reasonable and necessary
  - Regardless of what type of needle or technology used the challenges, selecting patients on who may benefit from this procedure
  - Two randomized controlled trials that had to look at these responses compared to placebo

        - Researchers have trouble selecting patients and trouble knowing which technology is most favorable
        - There's two RCTs that show treatment effects well beyond placebo, with roughly about 60% of patients achieving more than 50% pain relief, compared to the sham
    - Evidence
        - These studies show that 50 to 70% of patients get at least 50% pain relief. Patient's pain reduction at 18-24 months. Procedure that can mitigate the use of undesirable treatments
        - Over 20 studies now that reproduce the outcomes seen in the RCTs
- Neuroanatomical Consideration of SIJ Pain
    - There is complexity within this region. Complexity means that it is invitational or that it should be covered
    - SI Joint is not interchangeable
        - Different pain generations with different innervations should require different treatments
- L5 Dorsal Ramus and Sacral Lateral Branch Procedures
    - Publish RCT supports that sacral lateral branch blocks are predictive of outcomes
    - Diagnostic blocks have space validity
- Proposed Laminations
    - "SIJIs to treat non-specific low back pain {LBP), axial spine pain, complex regional pain syndrome, widespread diffuse pain, chronic pain syndrome, and pain from neuropath are considered investigational."
        - Language could possible be construed as excluding pain over the sacrum
        - Revise from "axial spine pain" to "axial spine pain primary above the level of L5"

Dr. Amol Soin

- All of the requirements are similar to sacroiliac joint injections with comparative controlled diagnostic blocks utilizing a short-acting and long-acting local anesthetic
- Positive response may be based on the same criteria as sacroiliac joint intraarticular injections
- Therapeutic L dorsal ramus and sacral lateral branch joint procedures are similar to intraarticular injections
- Request that procedure be added with similar criteria of two positive diagnostic blocks with concordant relief and providing six months of relief with each radiofrequency neurotomy with limiting for 2 per year in the therapeutic phase

Transtelephonic Spirometry

- New literature to support monitoring for lunch transplant recipients
    - Adherence to home spirometry of at least 80%
    - Non-Compliant patients will be provided education regarding non-compliance

Urine Drug Testing

- Clarification of when defined tests are covered
- Presumptive and qualitative test typically involve testing for multiple analytes based on history and risk
- Medically necessary when there's a need for immediate determination of the presence or absence of drugs
- Definitive/quantitative/confirmation is covered to find specific medication, illicit substance, or metabolite
- Point of Care Testing-Covered when immediate test results are needed

- Max number of allowed changed to rolling dates
- Blanket orders is non-covered
- Patient's risk category must be defined in the medical record and is essential to determining the appropriate number of urine drug tests build over time
- Opioid risk tool is one that is added to the policy as a suggested tool

Allergenic Hematopoietic Cell Transplantation for Primary Refractory or Hodgkin's and Non-Hodgkin's Lymphoma with B cell or T cell Origin

- Coverage criteria
    - Covered for patients with primary refractory or relapse of Hodgkin's or non-Hodgkin's lymphoma with B-cell or T-cell origin
    - Patients whose pre-transplant assessment indicates good functional status
    - Low comorbidities and the patient is a candidate for transplantation, and there is no other treatment options available with a curative intent

MolDX: Molecular Biomarker Testing Guide Targeted Therapy Selection in Rheumatoid Arthritis

- Requires that the test is performed by a board certified or board eligible dermatopathologist
- The specimen includes an area representative of the lesion or portion of the lesion that is suspicious for malignancy
- The patent may be subjected to additional intervention, such as re-excision and/or sentinel lymph node biopsy, as a result of the diagnostic uncertainty
- Technical assessment and clinical validity

Dr. Sam Asgarian

- Prism RA has been clinically validated in over 800 patient samples with a reporting PPV rate of 90%
- Over 100 rheumatologists submitted letters directly to Palmetto GBA's Open Meeting comment period. If possible, please review the formal comments
- Inadequate control of a patient's rheumatoid arthritis, results with inflammation that leads to joint damage, permanent disability, or health outcomes, including shortly expectancy

Skin Substitutes for the Treatment of Diabetic Foot ulcers and Venous Leg Ulcers (DL36690)

- Defined by the CPT Manual-A graph that can include non-autologous, human skin, graft, non-human skin substitute, or biologic product that forms a sheet scaffolding for skin growth.
- Skin substitute graph application codes are not to be reported for applications of non-graph wound dressings.
- Changes include updates to the title, changes to the history/background, update to the regulation of the products to provide definitions, utilization guidelines, updates to the bibliography to reflect current literature, and formatting changes

John McGinnis

- Clinical guidelines do not include a limit on skin substitute applications and evidence does not support a limit of 4 applications.
- Guidelines for both VLU and DFU do not indicate a maximum number of applications for specific skin substitutes. This will vary depending on the type of skin substitute.

- Only bases for limited the number of skin substitutes applications is Medical Necessity
- Recommend frequent evaluation at 1–4-week intervals with measurements of diabetic foot wounds to monitor reduction of wound size and healing progress.
- Limiting should be allowed when medical necessary
- Physicians should be able to consider using a different skin substitute, if the current, what's not working. The mechanism of action with the first can substitute is not causing the wound to heal.
- Prohibition on Reapplication if a Previous Application was Unsuccessful
    - If one application fails, it is clinically appropriate, and consistent with professional society guidelines to switch to a different skin substitute, especially one that is technologically different
- Prohibition of Application of Skin Substitutes in Patients with Inadequate Control of Underlying Conditions
    - Patients with uncontrolled conditions such as diabetes are exactly those patient who need skin substitutes the most if their diabetic ulcer does not heal with standard wound care
    - Patients with diabetes and other underlying conditions hat may not be well controlled still have effective immune systems and he capability to heal their wounds with the use of skin substitutes
- Puraply Products Are Improperly Assigned to Group 3
    - PuraPly products are cleared by the FDA under 510(k)
        - Equivalents are assigned to Group 2

<u>Dr. Jaideep Banerjee</u>

- Observations & Recommendations
    - The LCD should align with all of the findings that the LCD cites which supports maintain the current CGS rule and permits 10 skin substitute applications for different wound size
    - Should be based on medical necessity instead of the number of applications
    - Permit proof of wound progression for payment authorization after a certain number of applications
    - Allow for clinical necessity to drive the number of applications for complex wounds which take longer to heal
    - Allow products to be reimbursed only with supporting high level evidence
    - Allow for switching between skin substitutes with different physical properties that show clinical benefits to changing wound dept and wound progression
- Comments
    - Medical necessity should not be determined by an average number, but dependent on the person on the on the patient or the wound and also dependent on the product
    - Considering an average puts risk patients who have a large number of comorbidities or who have much larger wounds or who have much longer time
    - Care should be specific to each patient depending on the initial size of the wound

<u>Dr. Karen Ravitz</u>

Coalition of Wound Care Manufacturers recommends that CGS pull this draft and work stakeholders to create a more accurate and well-balanced policy that is based on the most currently available evidence.

- 4 application limitation is arbitrary
- Evidence cited in this policy either shows the number of applications to be higher than the four permitted under this policy or is clear that the number of applications should be based on the labeling instructions for the specific product being used

- Consider medical necessity based on progression

Skin Substitutes are not supplies

- Should not be referred to as supplies
- There is not other supply that requires the same level of documentation
- There is no other supply that has specific Joint Commission recommendations are tracking requirement

Evidentiary Requirements for Product Coverage Are Lacking

- There is no information contained in the LCD as to why some products are non-covered
- There is no information as to what specific evidence is required to be on eh covered list

Closing

Written comments needs to be accompanied by the evidence to support the comments in the form of published literature in PDF format.

Comments are due by November 19, 2022