CGS J15 Joint Kentucky & Ohio Open Draft/Revised LCD Discussion

Meeting Date and Time:	February 23, 2021 at 3:00 pm CST
Facilitator:	Dr. Meredith Loveless
Location:	Teleconference
Attendees:	Not to disclose

Dr. Loveless explained that polices that are proposed polices are discussed at the open meeting. Presenters sometimes share additional information about the topic, but there are no presenters today. The polices that are discussed today are open for comment and comments can be submitted to: CMD.INQUIRY@cgsadmin.com mailbox until April 4, 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 Policies Discussed

DL38201 - Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)

This is a new policy that recently became effective. Several of our providers inquired about the malignant fractures which were not included in this original policy that focused on osteoporotic vertebral compression factors.

So, while we were still covering the malignant fractures where appropriate, it was not addressed specifically in the policy and that resulted in some confusion regarding coverage.

In response to that input, we expanded the evidence section of the policy and added in the billing and coding for the for the vertebral compression fractures related to malignancy so that there would be no confusion regarding this topic. There were no other changes to the policy in terms of the osteoporotic, vertebral compression fracture portion of the policy.

The malignancies codes that were added into the policy for coverage were reviewed.

Billing and Coders should code the malignancy code with the code for a pathological fracture. This will inform that the fracture is being caused by the cancer, which would then meet the meet the criteria. The policy goes into the evidence of why these particular malignancies met reasonable and necessary criteria.

DL38920 - Off-label Use of Rituximab and Rituximab Biosimilars

This is a new policy that address the use chemotherapeutic agent rituximab and rituximab biosimilars.

This policy is not for use of anti-neoplastic conditions.

Please refer to A58113 - Off-Label Use of Anti-Cancer Drugs and Biologicals for cancer indication.

This policy originated from several request from our provider community for a variety of different coverage for Rituximab and non-cancer indications.

There are some definitions that are important to understand, and this is also important when it comes to documentation.

Off label use of the rituximab and rituximab biosimilars are for conditions that are refractory or refractory to first line treatment or for relapse disease that is not responding.

- First line therapy would be your standard of care (usually used to treat the condition as the initial treatment
- An adverse event would be when somebody is unable to take that medication or there are side effects that prevent them from being able to continue or use that medication or treatment.
- Lack of efficacy means that we're not getting the expected or desired effects of the medication when it's at standard dosage and duration.
- Refractory disease is when the patient fails to respond to all first line therapies that are standard of care.
- Relapse disease as recurrence of the disease condition that does not respond to first line treatments or standard care.
- When we refer to the treatments with Rituximab, the expectation is the patient was treated with standard doses as defined by the medical literature for the condition.

After the initial treatment, if there's a determined to need for re treatment, we do require a positive response to Rituximab to be documented in the record.

Conditions reviewed for the policy DL38920 - Off-label Use of Rituximab and Rituximab Biosimilars

The evidence review with the medical literature and rationale for the decision making within the policy.

- **Hemophilia** is one of the few conditions in which there may be indications for first-line use. This may be considered a patient with acquired or refractory hemophilia as first line combined with corticosteroids, and it also may play a role in second-line agents.
- **Immune thrombocytopenic purpura (ITP)** has a specific policy to address ITP and Rituximab is included in that policy. Please refer to LCD L38268 Immune Thrombocytopenia (ITP) Therapy.
- **Thrombotic thrombocytopenic purpura (TTP)** - Acquired Rituximab is appropriate if the patient has severe, refractory, or relapse TTP that had failed first line therapy.

  We do not consider the use for initial therapy or relapse prevention.
- **Autoimmune hemolytic anemia (AIHA)** this may be covered first line with symptomatic, severe cold AIHA.

  It would be considered second line for refractory warm IHA.
- **Evans Syndrome** is considered second line treatment after failed response to first line
- **Multiple Sclerosis** second line option for refractory or remitting, Multiple Sclerosis that failed first line therapy
- **Bullous pemphigoid** Rituximab may be considered in cases of refractory bullous pemphigoid, which has failed first line therapy
- **Membranous nephropathy** may be considered this indicates a refractory, or resistant Membranous Nephritis.

  This would be with Proteinuria of at least five grams for 24 hours of at least 40 MLs per minute and inpatient to have received angiotensin system, aids, blockers, for at least three months.

  Otherwise, this is considered as investigational for first line use
- **Immunotherapy-related Encephalitis** would be considered with positive autoimmune and satellite antibodies and limited, or no improvement work first line therapy.
- **Myasthenia Gravis** May be considered for MuSK-positive myasthenia gravis who have had a satisfactory response to initial therapy.

  In refractory AchR antibody in patients who fail or do not tolerate other immunosuppressive agents.

Is considered as investigational for initial treatment.

- **Neuromyelitis Optica** is considered investigational for first line.
- **Lupus nephritis** is considered investigational for first line but may be considered in refractory cases, defined as at least six months of conventional therapy with failure of standard treatment despite at least three months of tree of glucocorticoid, plus standard chemotherapeutic agent.
- **Minimal Change Disease** may be considered in children with steroid dependent steroids sensitive, nephritis Syndrome with relapsing disease despite optimal combination of steroids and other agents or serious adverse effects.

  May be considered in adults with relapsing, disease who failed to attain a durable remission with cyclophosphamide are healthier and inhibitors.

  This investigational and adults with glucocorticoid-resistant minimal change disease, as well as for first- or second-line therapy for minimal change disease.
- **Antibody-medicated rejection (AMR)** would be considered second line, or as part of a combination treatment for rejection and kidney long cardiac transplant.

  It may be considered in highly sensitive patients as part of the desensitization protocol while awaiting donor transplants.

  Other uses are considered investigational
- **Hematopoietic Stem Cell Transplant** may also be considered part of combination treatment for pre-operative, rest regiment or post-transplant for hematopoietic stem cell transplant patients

  Graft vs. Host Disease may be considered in cases of chronic disease, but investigational for first line.

The following are considered as investigational and are included for Non-Covered:

- Anti-synthetase syndrome
- Bechet's syndrome
- Cerebral Ataxia
- Polyarteritis Nodosa
- Sjogren's syndrome

Documentation Requirements

Many of these cases are limited to refractory or resistance. It's important that the records reflect adequate documentation:

The medical history, pertinent tests and procedures, office visits in any operative report.

Previous treatment, including dosing and frequency of treatment, duration of treatment and documentation of response, is a very important aspect of documentation.

The duration of the disease course, as well as the response to previous treatment.

Documentation must show that the previous treatment did not work.

- Was there a lack of efficacy, and if so, what was tried the dosing frequency duration, and what happened?
- If there is an adverse reaction, what was the reaction?
- Why would that prohibit continued use of the standard agent for refractory disease?
- What were all of the first line treatments use dosage and frequency as well as duration and the response?

Relapse disease-previous first line treatment, dosing frequency, duration, and response, and any clinical exam history or test resort, results that support relapsing disease.

Response to treatment at the time of relapse, including duration, dosing, and response.

Retreatment, documentation to support they had a positive response to treatment previously.

There's continuing change in the evidence and that some of these are being investigated for first line use. At this point, there's just a small amount of literature often limited to case reports and

case series. If evidence emerges that a provider feels would support coverage, that evidence can be submitted under the LCD reconsideration process.

The LCD reconsideration processes is outlined on our CGS website under medical policy. CGS is open to review that evidence and that evidence does need to be published in peer reviewed journals.

Please submit supporting documentation during the comment period through April 4, 2021 for areas the policy did not review, an article or literature that may support a difference.

Questions

Marcia: If a patient is on Rituximab for an off-label indication, will they be grandfathered into coverage or will they need to provide documentation?

Dr. Loveless: This will be subject to edit, so they will need to submit documentation and grandfathered cases are not identified. Be aware of the documentation requirements that are listed in the policy.

If they are on rituximab, there should be a positive response to the previous treatment, so that we can identify that it would be appropriate to continue.

Closing

Please send comments to CMD.INQUIRY@cgsadmin.com.

We are hopeful and optimistic that we may be able to resume meeting in person by summer or fall.

We appreciate you being on with us today and your input and involvement throughout this process.