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ILLINOIS, MINNESOTA AND WISCONSIN JURISDICTION 6

CONTRACTOR ADVISORY COMMITTEE MEETING

October 17, 2018

Minutes

Present:

Name	Organization/Business Represented
Olatokunbo Awodele, MD	National Government Services
Murad Alam, MD (Webinar)	Dermatology (Illinois)
Alicia Barling (Webinar)	National Government Services
Susan Bentz (Webinar)	National Government Services
Stephen Boren, MD (Webinar)	National Government Services
Michael Bottcher, MD (Webinar)	Anesthesia (Wisconsin)
Eric Brodsky	MGMA (Illinois)
Laura Brown (Webinar)	National Government Services
Charles Bush-Joseph, MD (Webinar)	Orthopedics (Illinois)
Lyle Coleman, DC (Webinar)	Chiropractic (Minnesota)
Gary Copland (MN Co-Chair) (Webinar)	Pathology (MN)
Jacqueline Cory, MD (Webinar)	Otolaryngology (Illinois)
Eugene Cropp, OD	Optometry (Wisconsin)
Jeffrey Crowhurst, DPM (Webinar)	Podiatry (Illinois)
Carolyn Cunningham, MD (Co-Chair)	National Government Services
Paulette D'Elia, RN (Webinar)	National Government Services
Viktoria Davis, OD (Webinar)	Optometry

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Leonora DeLong, RN (Webinar)	National Government Services
Amy Derick, MD (Webinar)	Dermatology (Illinois)
Katherine Dunphy (Webinar)	National Government Services
Michael Dorris (Webinar)	National Government Services
Marc Duerden, MD	National Government Services
Kathleen Hansen (Webinar)	Clinical Laboratory (Minnesota)
Craig Haug, MD (Webinar)	National Government Services
William Hartsell, MD (Webinar)	Radiation Oncology (Illinois)
Ibad Jafri (Webinar)	Office of Senator Amy Klobuchar (Minnesota)
Thomas Jendro (Webinar)	Illinois Health and Hospital Association
Timothy Johnson, MD (Webinar)	Emergency Medicine (Minnesota)
Craig Langman, MD (Webinar)	Nephrology (Illinois)
William Lissner, MD (Webinar)	Ophthalmology (Illinois)
Gary MacVicar, MD (Webinar)	Oncology (Illinois)
Anthony Marinelli, MD (Webinar)	Pulmonology (Illinois)
William Matthaeus, MD (WI Co-Chair)	Hematology/Oncology (Wisconsin)
Janice McMahon, OD (Webinar)	Optometry (Illinois)
Steven Merckx, DPM	Podiatry (Wisconsin)
Joseph Messer, MD (IL Co-Chair) (Webinar)	Cardiology (Illinois)
Cristopher Meyer, MD (Webinar)	Radiological Surgery (Wisconsin)
Gordon L Mortensen, MD	Pain Management (Wisconsin)
Virginia Muir (Webinar)	National Government Services
William Pao, MD (Webinar)	Radiation Oncology (Wisconsin)

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Maunak Rana, MD (Webinar)	Pain Management (Minnesota)
Jean Roberts (Webinar)	National Government Services
John Schilling, MD (Webinar)	Pulmonology (Wisconsin)
David Schultz, MD (Webinar)	Pain Management (Illinois)
Peter Shultz, MD (Webinar)	Pain Management (Illinois)
Theresa Schultz, Ph.D. (Webinar)	Psychology (Illinois)
Linda Solis (Webinar)	National Government Services
Elli Song (Webinar)	Office of Congressman Mike Quigley (Illinois)
Lynn Steffes, PT (Webinar)	Physical Therapy (Wisconsin)
Kim Thomas (Webinar)	National Government Services
Mimi Vier	National Government Services
Dan Virnig, MD (Webinar)	Gastroenterology (Minnesota)
Dianne Willer-Sly, APRN (Webinar)	Nursing Association (Minnesota)

TOPIC	DISCUSSION
1. ***Welcome***	The meeting was held at Anthem Corporate Facility, N17 W24340 Riverwood Drive, Pewaukee, Wisconsin and called to order by Dr. Matthaeus at approximately 4 pm. Dr. Matthaeus asked all attending in the room to introduce themselves. Mimi Vier announced the names of those attending by webinar.
2. ***Review and Approval of Past Minutes***	The minutes from the June 20, 2018 had been previously emailed to members asking for suggested changes or deletions. There were no responses so the minutes were considered approved. Work is still in progress to get them on the web for sending to professional societies and viewing by the public.
3. ***Local Coverage Determinations***	The presentation slides, referred to in the minutes, are attached here:  J6 PPT-October 17 2018 CAC.zip

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	One draft revised LCD and two new draft LCDs were presented. The official comment period extends to November 30, 2018. **Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (DL37810) – (Slides 7 – 11)** Dr. Haug explained that we were revising the existing policy developed for lung cancer (Genomic Sequence Analysis for Non-Small Cell Lung Cancer - L36376) to include new coverage for metastatic colorectal cancer (mCRC) panel testing. He noted colorectal cancer is the second leading cause of death from cancer in the United states and that 20% of patients present with metastatic disease. Six gene tests noted in evidence-based clinical guidelines to be clinically efficacious for individuals with mCRC are listed in the draft LCD as well as proposed indications and limitations. Comments were requested especially from oncologists or pathologists. Dr. Matthaeus, an oncologist, had reviewed the draft and thought the listed tests were appropriate for a patient with mCRC. The LCD restricts testing of genes to once/lifetime but does allow for exceptions. Concordance between initial tissue and metastatic tissue samples is thought to be about 90% so if initial KRAS and related marker testing was performed, a re-biopsy should usually not be needed. More than five markers may be measured in the next generation sequencing (NGS) panel, but only six are currently considered medically necessary. Dr. Virnig, a gastroenterologist, stated he supported the draft LCD as did Dr. Bush-Joseph. There were no negative comments. **Transvenous Phrenic Nerve Stimulation in the Treatment of Central Sleep Apnea (DL 37927) (Slides 12 – 18)** Dr. Cunningham reviewed definitions of central sleep apnea (CSA), obstructive sleep apnea (OSA), and mixed/complex sleep apnea as well as the criteria for apnea and hypopneas, and apnea-hypopnea indices (AHIs) for mild, moderate and severe sleep apnea. The draft addresses those who do not have neuromuscular disease but do have

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	heart failure or some other form of heart disease. There is not good treatment for these individuals. The American Academy of Sleep Medicine (AASM) considers nocturnal oxygen standard treatment and that BIPAP may be considered. In October 2017, the FDA approved a transvenous phrenic nerve stimulator for central sleep apnea. Four papers, one for feasibility, followed by another looking at 57 patients for six months, followed by a randomized controlled trial with 151 subjects were available for FDA review. In the last trial, all had the stimulator implanted but one group did not have it turned on until seven months into the study. Results showed a statistically significant lowering of the AHI, but it still remained in the moderately severe range. There was a trend towards improvement in measures of sleep quality and quality of life. There are no studies that show the primary treatment of CSA has improved outcomes in patients with heart failure. The draft proposes non-coverage. Dr. Haug reported that a specialist in the area had favored non-coverage at the JK meeting. Dr. Marinelli, a pulmonologist, had reached out to several board-certified polysomnography trained specialists and had gotten mixed comments. He noted the studies showed there had been some improvement in quality of life metrics and AHI, but the latter still remained in the moderate area. He stated he was comfortable with more study and had reached out to the ATS and ACCP for society opinions which he anticipated would come in written format. Dr. Schilling, a pulmonologist from Wisconsin with ATS, stated he agreed that there is not enough evidence to support coverage. He noted there was an article in 2016 from the American College of Cardiology suggesting there was some improvement using the device but that a larger study was needed. An official statement from the Wisconsin ATS is being sought. Dr. Corey, an ENT specialist who treats patients with obstructive sleep apnea stated she was not that familiar with CSA but thought it was fairly common for patients to have both OSA and CSA. She thought that having this modality available might allow the patient to

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	improve cardiac or lung function and that just because the patient is not being cured doesn't mean it should not be used. Dr. Messer had comments which he characterized as philosophic as much as scientific. As a cardiologist he sees patients with sleep apnea and thinks more research is needed in this area and if funding would help with increasing research, it would be a laudable goal. He would like to know the CSA effect on cognitive decline which he thinks has not been very well studied and what the effect of this device has been. Dr. Corey stated there was evidence of improvement with short-term memory functions with treatment of OSA and improved oxygen levels. Dr. Haug asked what the effect of avoiding the use of ASV in patients with low ejection fractions had been. Dr. Messer pointed out that there is still the option of CPAP and BIPAP. A question of whether the AASM had addressed this treatment and the answer was it is not included in the applicable guidelines. **Biomarker Tests for Neuroendocrine Tumors/Neoplasms (DL37858) (Slides 11 – 14)** Dr. Boren noted that this draft LCD addresses NETest, a specific proprietary test which is an Administrative Multianalyte Assays with Algorithmic Analyses (MAAA) code. It tests 51 genetic markers and then a proprietary "black box" estimates the likelihood of tumor presence. Seventy-three (73) articles have been provided. Each has been authored or co-authored by two individuals from Wren laboratories where the test was developed. He stated there has been no independent validation of the test. A search for studies showing improved outcomes in patients with carcinoid tumors has not been positive. Several letters, some from physicians in Europe have been received. The draft proposes non-coverage. Dr. Virnig, a gastroenterologist, stated his GI colleagues often have to deal with proprietary tests which have not been independently validated and may not be better than those which we have. He favors non-coverage until there is such validation or endorsement by the

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	AMA, a large GI professional society, etc. Dr. Haug noted that a pathologist at the JK meeting stated he thought that CAP and/or AMP would also have a similar position.
4. Category III CPT Codes and Other Updates, effective January 1, 2019	The new codes with a link to their description were presented on slide 27. Guidelines for cellular and gene therapies have also been added. Slide 28 includes links for the new MAAA and PLA laboratory codes. There was no discussion or comments.
5. Local Coverage Determination Process Changes	Dr. Awodele addressed changes in the LCD process that CMS is making as a result of the 21st Century Act passed in 2016 and are to be implemented by January 8, 2019. Changes were presented by showing the "old" (current) and the "new" processes. A summary of changes is as follows: • New LCDs and LCD reconsideration requests can be made with submission of supporting peer-reviewed literature. A decision of the request being valid or invalid will be made in 60 days. There is no required timeline for development of a new LCD or LCD revision. • CPT/HCPCS and ICD-10-CM codes will be removed from the LCD and put in coding articles. • Consultations with physicians or other experts will need to be included in the LCD with a summary of recommendations. • The LCD discussion portion of CAC meetings must be open to the public who can listen but not speak. All proposed new LCDs or those being changed due to reconsideration requests must be presented at an Open LCD meeting open to the public who can comment. Only controversial or complex LCDs need to be taken to CAC meetings which are optional. A CAC is required. The need for CAC members to provide information and resources that will strengthen the evidence base of the LCD was stressed. A member asked the reason for the changes. Increase in transparency is one reason given.

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	The need to record the Open LCD and the portion of the CAC meeting open to the public was discussed. It was acknowledged that these recordings will need to be available to the public. There was a lot of discussion about the plan for future CAC meetings. It was acknowledged that there is currently a lot of uncertainty. Removal of coding from the LCDs was of great concern to many. Members questioned whether these changes will promote transparency. Please refer to slides 22 - 26 for the above presentation.
6. Medicare Legislative Update	Michael Dorris presented a legislative update. Please see slides 29 – 45. He focused on changes that CMS has proposed and NGS is working to implement. He described a change in Minnesota law passed for Medicare Cost plans which are similar to Medicare Advantage plans that are going away. About 250,000 people will be affected. Mr. Brodsky, Executive Director of the Illinois MGMA, offered to send any information or surveys to members that would be helpful to NGS. He was asked if he might be able to work with the MGMAs in Minnesota and Wisconsin to do the same and he thought he possibly could. A question was asked whether physicians participating in Medicare but not Medicaid could balance-bill beneficiaries. They cannot unless there is a private contract or an opt-out of the Medicaid program which would allow direct billing
7. CERT Update	Dr. Cunningham provided a CERT update. Slide 47 shows the current estimated status for J6 and JK. (Color key: JK – lime green, bright red – J6, salmon – J6B, light blue- J6A.) It is anticipated that JK will have the best scores nation-wide. Last year, J6 had the second best. J6 Part A includes a large home health/hospice population which has a higher error rate that the other Part A programs. Review of J6 Part B errors shows them to be primarily E&M errors.

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8. Open Forum	No additional discussion.
9. Adjournment	The next meeting date is to be determined. The meeting was adjourned at approximately 6 pm.