MSSNY COMMITTEE ON INTERSPECIALTY
Thursday, June 28, 2018

Approval of the Minutes of the March 1, 2018 Committee meeting

Dr. Steven S. Schwalbe, presiding, called the meeting for June 28, 2018 to order. The first order of business was to approve the minutes from the last meeting held on March 1, 2018. The minutes were accepted and approved as written.

Medicare Legislative Update

Ms. Katherine Dunphy provided the Medicare update. In the material for the CAC there is a Medicare update. The material can be found here: https://bit.ly/2uZxxzJ

The first item concerns the mailing of the **new Medicare cards** to all of the Medicare beneficiaries in the state of NY. NY State is in wave four of the national CMS mailing. That means we forecast that somewhere after July 25 or so that the US post office is going to deliver all of the NY Medicare cards for the Medicare beneficiaries in NY State. The number to identify Medicare is very, very much different. It is a mix of numbers and letters and the numbers are totally randomly selected. If a physician practice is enrolled in the NGS Connex portal, there is an online lookup tool that is very easy.

The transition period is just about over a full year from now, and if you file a claim with the old Medicare number even though the person has a new one, the claim will process. No benefits will be denied, and the Medicare remittance will contain the new number. Everyone needs to be aware of the new Medicare beneficiary numbers. If the practice is enroll in Connex, take advantage of the free online tool as long as you have an internet connection somewhere in your practice.

CMS came out with a new ruling for **teaching physicians** in March of this year for those of you who are treating people in academic environments where you have medical students. CMS is now going to allow the medical student to assist physicians by writing portions of the note. Physicians can have the students write the note as long as the physician reviews the note and is involved with treating the patient. It is less of a burden for people working in the academic world where you would be teaching a medical student in day to day practice.

Medicare files change all of the time and NGS has already received alerts that **ICD-10 updates** will be effective in October. This is planning ahead. ICD-10 updates are coming. Physicians can work with their specialty societies to identify the diagnosis code updates. CMS is already preparing for the October 1 update with regard to the National Coverage Determinations, just an important reminder going forward. The specialty societies should be able to assist practices in looking for the diagnosis codes that would affect your practice. There should not be as many as there were last year, because of the timing of the transition of ICD-10. But, practices should be aware of updates to avoid any coding problems.

Next, Kathy reiterated the new NGS Medicare process of **Targeted Probe and Educate**. NGS is working on a massive project to analyze the data of the claims that we process more thoroughly. This new medical review process is much more efficient and much more user friendly because it now includes education - one on one/direct education.

NGS Medicare is continuing many efforts to reduce provider burden. Appeals analysis has shown that issues with **Medically Unlikely Edits (MUEs)** are the highest reason for Medicare Part B Appeal receipts. These edits are nationally set by a CMS contractor, National Correct Coding. Inquiries about the MUE program other than those related to MUE values for specific HCPCS/CPT codes should be sent to the following email address:

NCCIPTPMUE@cms.hhs.gov.

Educational articles and webinars have been developed to assist all providers. Increased awareness and review of the edits for your specialty is advised. NGS really wants to promote the analysis tools that have been worked on and move forward to make it easier to deal with Medicare claims and reduce the provider burden. The tools should be used by the medical practicesø billing staff and physicians will be able to deal with the Medicare system a lot easier and simpler.

2018 Outpatient Therapy Services
Bipartisan Budget Act of 2018 included several provisions related to Medicare payment. The law repealed the 2018 outpatient therapy caps of $2010. The cap amounts will be used as a threshold. Claims over the threshold must include the KX modifier.

Targeted Medical Review Process
The threshold for the manual medical review has been lowered to $3000 from the $3700 threshold. Claims are not automatically subjected to a targeted medical review. Providers who have a high claim denial rate or aberrant billing patterns will be reviewed.

NGS Contact Information

Telephone Contact: JK 866-837-0241

Correspondence: National Government Services
Part B Provider General Written Inquiries
P.O. Box 6189
Indianapolis, IN 46207-6189

Provider Enrollment (JK): **888-379-3807**

Medicare CAC Local Coverage Determinations (LCDs) for consideration ó

Dr. Clark stated that before discussing the draft LCDs, CMS Medicare would like to know if the Committee Members, some of whom are CAC reps and/or alternate CAC reps, if there would be a problem if contact information was made public. This could result in physician members being reached by other members of the medical community or reached by anyone who is non-medical regarding decisions made by the Medicare CAC. CMS Medicare wants to know if that would that be a problem for Medicare CAC representatives.

Dr. Steve Lee Allen, Hematology, stated that members of his subspecialty reach him all of the time. He would have no objection to physicians being able to reach and comment on the CAC discussions. He would object to the public having access.

This is Dr. Naheed Asad-Van De Walle, Physical Medicine and Rehabilitation. She stated that this happened once before about the CAC meeting. Physicians are representing their specialties and different organizations so we can convey that message to the specialties. However, she is not in favor of disclosing the information about the CAC representatives or meetings to the public.

This is Dr. Allen C. Small, MD, Internal Medicine. He is not in favor of disclosing to the general public the information about the physician representatives to the CAC.

Dr. Clark explained that unfortunately in some ways, as you can see, Medicareøs policy developments are being driven by the device and diagnostics industry. We are getting some sort of internal pressures to work on coverage issues perhaps because the coverage and analysis group of CMS has not been funded to the degree that it has been in the past. There are some vacancies for medical officers who are interested in research and coverage analysis.

This past CAC meeting was well attended. But, CMS is looking at the efficacy of the CAC process. And I now have gotten some communication this morning that there is going to be some manual changes pertaining to Medicare coverage coming up this summer. Dr. Clark will keep members posted probably through MSSNY as these things come out.

The problem is there is a push to have clarity and transparency of the minutes. However, actively practicing physicians who voluntarily give of their time to speak to the medical necessity of policies do not need staff from the device and diagnostics industry coming to their offices to lobby for their agenda. In addition, there is a moderate Republican group is asking the Commissioner of HHS to justify the spending in this past year, particularly on acknowledging, and that spending may not be totally justified. Dr. Clark will keep the members posted as this plays out.

Now, the LCDs -

Biomarker Testing for Prostate Cancer Diagnosis (DL37733)

Only about 25% of men with PSA in the 4-10 ng/mL range have prostate cancer on biopsy, and of those, about 20-50% are indolent, disease that would not be a problem if undetected or untreated. Therefore, the current focus is on finding a more nuanced approach (beyond PSA and digital rectal exam (DRE)), by reserving biopsy and treatment for men with clinically significant, higher-grade (Gleason × 7) prostate cancer (HGPCa). This strategy has the potential to not only decrease biopsies (and associated risks), but also of reducing detection of indolent disease (and the attendant risks of overtreatment).

The number of assays purported to serve as a useful adjunct to PSA in HGPCa prediction is mounting rapidly. There is some guideline consensus, if tepid, around the clinical utility of three: %f PSA, PHI, and 4Kscore. Benefits remain theoretical, namely, that fewer biopsies of men with moderately elevated PSA is inherently a good thing. Certainly, it is good in the short term for men who avoid an õunnecessaryö prostate biopsy. Not good, however, are necessary biopsies missed due to false negatives. The long-term benefit of these tests to net health outcomes (i.e., mortality, morbidity, or quality of life) is not yet clear.

Given the state of flux of PSA screening in general, combined with only vague and lukewarm guideline support (secondary to the absence of Level I studies), NGS will provide very circumscribed coverage limited to patients with moderately elevated PSA levels, but with no other, even relative, indication for or against biopsy (largely based on NCCN guidelines). These are men for whom the decision about whether to proceed with prostate biopsy is most ambiguous, and therefore for whom the information is most likely to impact clinical decision making.

ONE biomarker test (%f PSA, PHI, or 4Kscore) is covered **ONCE** in patients with confirmed* moderately elevated PSA (>3 and <10 ng/mL) with **BOTH** the following:

No other relative indication for prostate biopsy including **ANY** of the following:

DRE suspicious for cancer

Persistently elevated PSA

Prior prostate biopsy
Positive multiparametric MRI (if done)
Other major risk factor for prostate cancer including: Ethnicity at higher risk for prostate cancer
First-degree relative with prostate cancer
High-penetrance prostate cancer risk gene(s) per NCCN (if known)

No other relative contraindication for prostate biopsy including **ANY** of the following:

Age >75
<10 year life expectancy
Benign disease not ruled out

Water Vapor Energy Ablation (WAVE) for LUTS/BPH (DL37757)

WAVE uses convective water vapor energy to ablate prostatic tissue. Unlike conductive thermal ablation (TUNA, TUMT), steam convection at a physical phase change boundary best realizes a õprescribed temperature boundary conditionö, effectively precluding a temperature gradient beyond the targeted prostate (usually the transition zone). This was confirmed by histologic and imaging studies using gadolinium enhanced MRI. According to the manufacturer, WAVE requires õfewer joules per gram of tissue, ~1/6ó1/23, to produce cell necrosis in prostate tissue compared to TUNA and TUMT, respectively.ö

Longstanding American Urological Association (AUA) guidelines considered both TUNA and TUMT õan appropriate and effective treatment alternative for bothersome moderate or severe LUTS secondary to BPH." However, just-issued, new guidelines no longer recommend TUNA based on õexpert opinion,ö and õconditionally recommendö both TUMT and WAVE (õevidence level: Grade Cö). The WAVE statement, based on the one RCTøs two-year data, is particularly cautious, noting õpatients should be informed that evidence of efficacy, including longer-term retreatment rates, remains limited.ö

Compared to TUNA and TUMT,WAVE data is limited in time (mid-term), scope (no studies comparing WAVE to other surgical options), and independence (no studies independent of manufacturer funding, and at least some author conflict of interest). The lack of long-term results is particularly important in view of the relatively low IPSS and Qmax percent improvement after WAVE at 3 years. Especially concerning is the sudden drop in Qmax improvement (53% to 39%) between years two and three, as this objective outcome metric is less subject to the placebo effect than IPSS. Although still significantly improved from baseline, the trajectory is troubling. Mid-term results suggest that durability after WAVE is no better, and may even be worse, than TUNA and TUMT. The new AUA WAVE recommendation based on one studyøs two-year data seems premature, especially in light of the subsequent Qmax drop from year two to three. Conversely, unlike TUNA and TUMT, WAVE offers the potential for a low morbidity treatment of median lobe LUTS. NGS, therefore, will tentatively cover WAVE treatment for LUTS/BPH, (with an obstructing median lobe) in poor surgical candidates, under criteria otherwise largely based on the RCT, pending long-term data.

ONE treatment for LUTS/BPH treatment is covered **ONCE** in patients with **BOTH** the following:

Indications including **ALL** of the following:

Age >50
Symptomatic despite maximal medical management including **ALL** of the following:
International Prostate Symptom Score (IPSS) ×13
Maximum urinary flow rate (Qmax) of Ö15 mL/s (voided volume greater than 125cc)
Failure, contraindication or intolerance to at least three months of conventional medical therapy for BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)

Prostate volume of 30-80 cc,

Obstructing median lobe,
Poor candidate for other surgical interventions for BPH due to underlying disease (e.g. cardiac disease, pulmonary disease, etc.), or at high risk of bleeding.

No contraindications including **ALL** of the following:
Prostate specific antigen (PSA) >2.5 ng/mL with a free PSA <25% (unless prostate cancer ruled out by biopsy)
Active urinary tract infection
History of bacterial prostatitis in the past three months
Urinary retention (e.g., PVR >250-300 mL, catheterization requirement, history of being unable to void)
Inadequate length prostatic urethra (<25mm)
Prior prostate surgery
Neurogenic bladder
Urethral stricture

Dr. John Phillips, Urology, was not available to comment on either policy. The official comment period for these two draft LCDs ends on August 8, 2018.
Comments can be sent to: PartBLCDComments@anthem.com

or

National Government Services, Inc.
LCD Comments
P.O. Box 7108
Indianapolis, IN 46207-7108

Prostate Rectal Spacers (L37485)
Dr. Clark stated that he understands that there was some disappointment from folks in Jurisdiction K regarding Prostate Rectal Spacer coverage.

Dr. Clark stated that NGS Medicare is not the only contractor not covering Spacer. However, the criticism is understood. NGS Medicare is going to open the process again for this LCD.

In the future, it should be understood that policies have to go through the process the timing. Upon the release of the policy, it is the medical communityøs immediate right to ask for reconsideration. Based upon the receipt of several articles that were in development and have now been released the contractor is aware that reconsideration will be sought. There was a recent AUA meeting in May. This policy was developed in our mid-western jurisdiction. Now the other contractors do not expressly cover Spacer. They are going to have come to some decision point and may do so with our reconsidered policy. This has generated a lot of interest. NGS Medicare will be undertaking reconsideration as soon as this policy cycle finishes.

Next, Mr. Morris (Moe) Auster provided the **Legislative Update.**
The Legislature finished or mostly finished their work for the year, last week. The last day of session was June 20th; more specific early in the morning of Thursday June 21st.
There were a lot of healthcare issues kind of below the radar that were receiving a lot of attention. Some of which MSSNY supported and many of which were opposed. These measures included a **statewide drug takeback program** for the safe disposal of medications that should be paid for by the pharmaceutical industry.
Another issue involved a bill that MSSNY and the NYS Psychiatric Association worked closely on. It is a bill that will require health insurers to provide data to the Department of Financial Services (DFS). Plans will now be required to send additional data that DFS advising how

insurers are complying with the **mental health/substance abuse parity** requirements that have been enacted in New York. This information will be included in DFSø annual consumer guide for health insurance.
Another bill MSSNY supported involved **Prostate Cancer Screening.** In this piece of legislation, the cost sharing requirements for Prostate Cancer Screening would be eliminated. It will also be more generous than the national level, since it would cover those who are asymptomatic, over 50 and have a family history of the condition. For those 40 and over, the bill would require insurers to cover the service.
Another bill that MSSNY worked closely with Dermatology Society and some public health groups changed the rules about who is eligible for use of **tanning beds**. Now, only those who are 18 and over would be able to use tanning beds.
Also, the state will continue confidentiality and liability protection for MSSNYøs CPH Committee until 2023.
MSSNY also received a grant for $100,000 for womenøs health issues.
MSSNY worked hard to defeat a bill requiring physicians to report patients to the DMV. Instead, the DMV will be required to request an assessment if they have any concern about a specific driverøs capability.
Moe provided the members with information about the updates to the Workersø Compensation Program. He mentioned the anticipated update to the physician fee schedule.

Questions arose about the cuts that will be occurring for the changes for Nerve Conduction Studies. MSSNY, PM&R and other specialties have voiced strong concerns about these cuts. The WCB has indicated that they have no intention of decreasing fees for any specialty treating injured workers. We will need to see what transpires with how the Board responds to the commentaries submitted by the various stakeholders.

Any specialty specific issues:
Dr. Martin Wolpin, Orthopedist, advised the members that an article appeared in the on-line version of the JAMA. The article was written by a Chiropractor. The article has been picked up by other medical publications. The article specifies that chiropractic is a very therapeutic and valuable source of treatment. Dr. Wolpin is questioning a non-peer reviewed, non-medical article being published in a prestigious medical publication. Dr. Wolpin questions the AMA supporting this type of publication.
Dr. Wolpin is seeking the support of some Committee members in writing to the editor of JAMA to question a non-peer reviewed, non-medical article being published in a respected journal. What are JAMAøs procedures in accepting non-physician, non-peered reviewed article supporting non-physician practitioners?

New York State Orthopedic Society drafted a letter which has been sent to the full Committee. Several specialties are lending support and agreeing to sign on to this letter to the editor of JAMA.

There being no additional business for todayøs meeting, the call was concluded at 12:00 noon. Dr. Schwalbe thanked the attendees for their participation and the call ended.

Respectfully submitted,

Steven S. Schwalbe, MD, Chairman