National Insurance Advisory Workgroup REPORT

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Conference call March 20, National Insurance Advisory Workgroup. Two main issues were BCG shortage and compounding of hazardous drugs.

The BCG shortage is expected to last through 2019. Merck is the only company that makes it and it is at 100% capacity.

The AUA is reaching out to the MACs for billing advice. Recommendation is to use ½ to 1/3 dose and split the vials between patients, knowing that you only have 4 hours of efficacy after reconstitution. The FDA is not fond of this as it is not how the drug is to be administered but they have no suggestions as to how to take care of all our bladder cancer patients either. Hopefully, the AUA will have some answers on billing from CMS soon.

One of the big "wins" at the advocacy conference in DC was the AUA reps meeting with US Pharmacopia about the compounding of hazardous drugs. At the present time, Lupron and BCG are on the list of "hazardous drugs" and may require special compounding situations, ie. a hood to mix them. The AUA reps made the point that we are not compounding, but administering the drugs. They have agreed to look into this so we will not be burdened with having to purchase hoods, etc.

February 13, 2019 Call

We spent some time discussing the new CAC rules which were reviewed at the Washington CAC meeting on 2/12/19. Presented at the bottom of this report.

BCG Shortage – worldwide. The AUA is working on this. Recommendations at present are to only treat induction cases (not maintenance) with ½ dose and to use valrubicin for maintenance but it is very expensive.

AUA Insurance Roundtable met at AUA HQ in Maryland on November 9. There were commercial insurers, MACs and a number of specialty society reps. It was considered a success in having people from these various stakeholders meeting face to face. Probably will be an annual event.

Summary for MM10901 and Change Request MM10901
CMS is trying to make the LCD process more transparent. Over the past year there have been a few changes starting with the 21st Century Cures Act (Public Law No: 114-255) (The law builds on FDA's ongoing work to incorporate the perspectives of patients into the development of new technologies). CMS revamped the format of the manual so that it could be used as a

roadmap to understand the steps of the local coverage process. This transparency also carries through to the reconsideration process.

Contractor Advisory Committee (CAC)
The CAC is to be composed of healthcare professionals, beneficiary representatives, and representatives of medical organizations; and is used to supplement the MAC's internal expertise, and to ensure an unbiased and contemporary consideration of "state of the art" technology and science. Additionally, all CAC meetings will be open to the public to attend and observe.

MACs will establish one CAC per state or one per jurisdiction with representation from each state, ensuring that each state has a full committee and the opportunity to discuss the quality of evidence used to make a determination.

The CAC's purpose is to provide a formal mechanism for healthcare professionals to be informed of the evidence used in developing the LCD and promote communications between the MACs and the healthcare community. The CAC is advisory in nature, with the final decision on all issues resting with MACs.
The key parts of the New LCD Process are summarized as follows:

1. The New LCD Process may begin with informal meetings in which interested parties within the MAC's jurisdiction can discuss potential LCD requests.
2. New LCD Requests
    a. The New LCD Request Process is a mechanism through which interested parties within a MAC's jurisdiction can request a new LCD. In this process, MACs will consider all new LCD requests from:
        - Beneficiaries residing or receiving care in the MAC's jurisdiction
        - Health care professionals doing business in the MAC's jurisdiction
        - Any interested party doing business in the MAC's jurisdiction

MACs will consider a New LCD Request to be a complete, formal request if the following requirements are met. The request:

- Is in writing and is sent to the MAC via e-mail, facsimile or written letter
- Clearly identifies the statutorily-defined Medicare benefit category to which the requestor believes the item or service applies
- Identifies the language that the requestor wants in an LCD
- Includes a justification supported by peer-reviewed evidence (full copies of published evidence must be included or the request is not valid)
- Addresses relevance, usefulness, clinical health outcomes, or the medical benefits of the item or service
- Fully explains the design, purpose, and/or method, as appropriate, of using the item or service for which the request is made.