November 7, 2018

Electronic Submission via DraftLCDComments@novitas-solutions.com

Novitas Solutions
Medical Policy Department
Union Trust Building
Suite 600
501 Grant Street
Pittsburgh, PA 15219

RE: Draft Local Coverage Determination for Hyaluronan Acid Therapies for Osteoarthritis of the Knee (DL35427)

To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) welcomes the opportunity to comment on the draft local coverage determination (LCD) for Hyaluronan Acid Therapies for Osteoarthritis of the Knee (DL 35427). The AANA offers comments in the following area:

PROVIDER QUALIFICATIONS SECTION

• Allow for the Reimbursement of Hyaluronan Acid Therapies Provided by CRNAs.

Background of the AANA and CRNAs

The AANA is the professional association for CRNAs and student registered nurse anesthetists (SRNAs), and AANA membership includes more than 53,000 CRNAs and SRNAs representing over 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 43 million anesthetics to patients each year in the United States. Nurse anesthetists have provided anesthesia in the United States for 150 years, and high-quality, cost-effective CRNA services continue to be in high demand. CRNAs are Medicare Part B providers and since 1989, have billed Medicare directly for 100 percent of the physician fee schedule amount for services.
CRNA provide every aspect of the delivery of anesthesia services including pre-anesthesia patient assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery. CRNAs also provide acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. According to a May/June 2010 study published in the journal of *Nursing Economic*, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.\(^1\) Furthermore, an August 2010 study published in *Health Affairs* shows no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.\(^2\) Researchers studying anesthesia safety found no differences in care between nurse anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review prepared by the Cochrane Collaboration.\(^3\) Most recently, a study published in *Medical Care* June 2016 found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.\(^4\)

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AANA Request: Allow for the Reimbursement of Hyaluronan Acid Therapies Provided by CRNAs

We request that this draft LCD allow for the reimbursement of medically necessary and appropriately used hyaluronan acid therapies provided by CRNAs. One study found that the use of intra-articular injection of hyaluronan acid derivates for the treatment of osteoarthritis has been use for over 30 years and is often used when other treatments have failed. Further review of the literature has demonstrated that the use of corticosteroids has shorter efficacy than hyaluronan acid for osteoarthritis of the knee, of which hyaluronan acid has been demonstrated to last several months. In a large retrospective cohort observational study of elderly knee osteoarthritis patients, using a five percent sample of Part B Medicare data from 2005 to 2012, researchers were able to illustrate that patients that underwent intra-articular injection of hyaluronan acid had prolonged the need for knee arthroplasty. In general, the median time to knee arthroplasty was 15.3-23.3 months for patient receiving intra-articular injection of hyaluronan acid and corticosteroids compared to 7.9-14 months for intra-articular injection of corticosteroids alone. New research suggests that concomitant use of hyaluronan acid and corticosteroids are more advantageous than single drug intra-articular injection alone. In a six-month follow-up of a randomized double blinded clinical trial of patients undergoing an intra-articular injection of a corticosteroids, hyaluronan acid, or hyaluronan acid and corticosteroids for osteoarthritis of the knee, the corticosteroids group had a significantly lower functional status score compared to the other groups. Overall, for patient with severe osteoarthritis of the knee, viscosupplementation showed improved functional status scores after three months of treatment with hyaluronan acid or hyaluronan acid and corticosteroids injections. Another randomized double blinded clinical trial also looked at formulations using intra-articular hyaluronan acid injections and single combination intra-articular hyaluronan acid and corticosteroids injections.

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7 Ong KL op cit.

and found that patients not only tolerated intra-articular hyaluronan acid and corticosteroids injections well, but also reported more rapid pain relief lasting over 26 weeks.⁹

Pain management is central to the scope and practice of a CRNA, and CRNAs play a vital role by providing patient focused, comprehensive pain care in communities throughout the United States. CRNAs provide pain management for patients who have been diagnosed with osteoarthritis, and these services are especially crucial to beneficiaries in rural areas who may not have access to other specialists. Denials for these services provided by CRNA would limit access to necessary pain management services for Medicare beneficiaries, especially in rural areas. Furthermore, Medicare regulations state: "Medicare Part B pays for anesthesia and related care furnished by a certified registered nurse anesthetist or an anesthesiologist’s assistant who is legally authorized to perform the services by the State in which the services are furnished."¹⁰

As professionals, CRNAs engage in life-long learning and quality improvement activities for safety and excellence in all aspects of patient-centered anesthesia care, including procedures for chronic pain management practice. CRNAs who provide pain management do so in accordance with their professional scope of practice, federal and state law, and facility policy. Furthermore, it is incumbent upon each individual health care professional to assure his or her competency when providing patient care, including pain management and treatment. Therefore, we request that this draft LCD allow for the reimbursement of medically necessary and appropriately used hyaluronan acid therapies provided by CRNAs.

We thank you for the opportunity to comment on this draft local coverage determination. Should you have any questions regarding these matters, please feel free to contact the AANA Senior Director of Federal Government Affairs, Ralph Kohl, at 202.484.8400, rkohl@aanadc.com.


Sincerely,

Garry Brydges, DNP, MBA, ACNP-BC, CRNA
AANA President

cc: Randall D. Moore, DNP, MBA, CRNA, AANA Chief Executive Officer
    Ralph Kohl, AANA Senior Director of Federal Government Affairs
    Romy Gelb-Zimmer, MPP, AANA Senior Associate Director Federal Regulatory and Payment Policy