Florida Society of Physical Medicine and Rehabilitation
5200 NW 43rd St, Suite 102-321
Gainesville, FL 32606
Phone: 352-226-8641 Fax: 352-240-6293
E-Mail: Lorry4@earthlink.net Web: fspmr.org

Blue Cross Blue Shield of Florida
Scott McClelland, Pharm. D.
4800 Deerwood Campus Pkwy
Jacksonville, FL 32246

April 28, 2015

Dear Dr. McClelland:

The Florida Society of Interventional Pain Physicians (FSIPP), joins the American Society of Rheumatology and the Florida Society of Rheumatology, on behalf of its membership to strongly disagree with your new policy of denying payment for Visco Supplementation (VS) as treatment for Osteoarthritis (OA) of the knee. This misguided policy runs counter to the experience of our members and to the best current recommendations in treating OA of the knee. Therefore, we urge you to reverse your new policy and re-establish payment for these important medications.

The rationale by which we protest and oppose your new policy is as follows:

1. Visco Supplements are FDA approved for use in the treatment of OA of the knee. Each brand of VS passed rigorous assessment by the FDA, a process that required extensive data from randomized, double blind, placebo controlled studies supporting their safety and efficacy.

2. You cite the 2013 Clinical Practice Guidelines (CPG) of the American Academy of Orthopedic Surgeons (AAOS) (1) in your rationale for removing VS from coverage. To begin, the AAOS work group, which authored the CPG considered only a fraction of the available literature at the time. Of 2,222 peer reviewed full length studies recalled for review, only 218 articles (< 10%) were included to formulate the recommendations on all potential OA treatments. The AAOS inclusion criteria allowed for only 14 visco-supplementation (VS) studies in the analysis. Of these studies, 3 were categorized as high strength and 11 were moderate strength. In addition, an independent literature search identified other RCTs that met criteria, but were not included in the review – for reasons unknown and unexplained. Clearly this sample does not represent the entirety of the VS medical literature. This may be the reason that the AAOS itself indicated that the CPG was not to be used as a coverage determination tool. In addition, there are a series of meta-analyses that do support the use of intra-articular VS. (See references 2 – 7)

3. Another meta-analysis supports the therapeutic effects of VS. In 2013, Larry Miller and John Block (8) analyzed 29 studies comprising results from 4,866 patients with OA of the knee who received either intra articular Hyaluronic Acid (HA) or saline injections. Their analysis demonstrated significant improvement in the HA treated group vs. the saline treated group. In addition, there were no significant differences with respect to serious adverse events or withdrawal.

4. **A more recent meta-analysis reported by Bannuru et al. in the January issue of The Annals of Internal Medicine demonstrated that intra-articular HA treatment was more effective than standard oral therapies. That meta-analysis analyzed 137 studies comprising 33,243 participants, and compared oral treatments with NSAIDs and acetaminophen to intra-articular treatments with HA, corticosteroids and saline solution for pain, function, stiffness and safety. The most significant conclusion of this meta-analysis was that HA treatment was the most efficacious therapy.**

5. Other recent data have demonstrated that intra-articular HA treatments delayed total knee replacement by 2.6 years in patients with knee osteoarthritis (9). It is confounding to the sensibility of good medicine and economics that you would promote early surgery by removing from our use a treatment that effectively delays it.

6. As you must know, we treat patients that cannot use anti-inflammatory medications, because of gastric ulceration or renal dysfunction or any number of other reasons. In addition, we treat patients that cannot or will not undergo surgical intervention for a variety of reasons. Taking VS out of the possibilities for treatment leaves these patients with no alternative for the treatment of knee OA. You are causing these patients to suffer, when VS could serve as an efficacious, cost efficient, clinically proven, evidenced based treatment for their OA.

Clearly, the AAOS Clinical Practice Guidelines possess methodological flaws, as demonstrated above. In addition, we have presented a wealth of current data supporting the safety and efficacy of US FDA approved Visco-Supplementation products for the treatment of pain associated with knee OA. The BCBS FL decision to discontinue coverage for VS will unnecessarily limit the safe treatment options to physicians and to BCBS beneficiaries and will likely shorten the time to knee replacement surgery. One can only hypothesize that such a policy would increase the cost of care for treatment of OA of the knee. We suspect that patients who wish to avoid knee surgery would more strongly consider purchasing another health insurance. Finally, you must know that the BCBS affiliates in North Dakota, North Carolina, Hawaii, Colorado, New Jersey, Pennsylvania, and Utah/Idaho have all recently reversed their decisions to remove VS from coverage. They are all now covering this treatment for OA of the knee. We urge you to re-establish coverage for VS for the treatment of OA of the knee.

Sincerely,

Michael J Creamer DO

The Florida Society of Physical Medicine and Rehabilitation
Michael Creamer DO
President
cc: Insurance Commissioner Kevin McCarthy

Florida Office of Insurance Regulation
200 East Gaines Street
Tallahassee, Florida 32399-0305
850-413-3140