

OHCA Guidelines

Medical Procedure Class:	Viscosupplementation /Hyaluronic Acid
Initial Implementation Date:	8/1/2015
Last Review Date:	7/26/2019
Effective Date:	10/1/2019
Next Review/Revision Date:	September 2022
<p>* This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.</p>	
<input type="checkbox"/> New Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria	
Summary	
Purpose:	To provide guidelines to assure medical necessity and consistency in the prior authorization process.
Definitions	
<p>Hyaluronic acid – also known as hyaluronan or hyaluronate, is a naturally occurring substance found in the synovial fluid surrounding joints.</p> <p>Osteoarthritis – degeneration of joint cartilage and the underlying bone, most common from middle age onward. It causes pain and stiffness, especially in the hip, knee and thumb joints.</p> <p>Viscosupplementation – the injection of hyaluronan or derivatives-hylans into joints to manage osteoarthritis, improve synovial fluid elasticity and viscosity and relieve pain.</p>	
Description	
<p>Osteoarthritic joints are found to have lower concentrations of hyaluronic acid. Intraarticular injection of hyaluronic acid, also known as viscosupplementation, has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in individuals with osteoarthritis. By adding hyaluronic acid to the existing joint fluid of an osteoarthritic knee via injection, the goal is to facilitate better knee movement, reduce pain, and perhaps slow osteoarthritis progression.</p>	
<p>CPT Codes Covered requiring PA: Hyaluronan or derivative J7321, J7323, J7324, J7325 and J7326 *****See HCPCS Book for full definition of codes*****</p>	
<p>Note: Only viscosupplementation injections of the knee will be reimbursed.</p>	
Approval Criteria:	
<p>Initial Injection/Series of Injections</p> <p>A. Viscosupplementation shall be considered medically necessary for members with osteoarthritis of the tibiofemoral articulation of the knee who meet all of the following selection criteria:</p> <ol style="list-style-type: none"> 1. Conservative therapy (including physical therapy or home exercise plan, pharmacotherapy {e.g., non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen (up to 1 gram four times/day), and/or topical capsaicin cream}), has been attempted for each joint to be treated with viscosupplements and has not resulted in functional improvement after at least 3 months, or the member is unable to tolerate conservative therapy because of adverse side effects; and 	

2. The clinical diagnosis is supported by radiologic evidence of osteoarthritis of the knee such as joint space narrowing, subchondral sclerosis, osteophytes and subchondral cysts, or if radiographs are not available, the member has documented symptomatic osteoarthritis of the knee according to the American College of Rheumatology (ACR) clinical and laboratory criteria, which requires knee pain and at least 5 of the following:
 - Bony enlargement
 - Bony tenderness
 - Crepitus (noisy, grating sound) on active motion
 - Erythrocyte sedimentation rate (ESR) less than 40 mm/hr
 - Less than 30 minutes of morning stiffness
 - No palpable warmth of synovium
 - Over 50 years of age
 - Rheumatoid factor less than 1:40 titer (agglutination method)
 - Synovial fluid signs (clear fluid of normal viscosity and WBC less than 2000/mm³); **and**
3. The member has failed to adequately respond to aspiration and injection of intraarticular steroids or has a medical reason for not being able to utilize steroid injections; **and**
4. The member reports pain which interferes with function activities (e.g., ambulation, prolonged standing); **and**
5. The pain cannot be attributed to other forms of joint disease; **and**
6. The member is not scheduled to undergo a total knee replacement within 6 months of starting treatment; **and**
7. There are no contraindications to the injections (e.g., active joint infection, bleeding disorder, skin infection at the injection site).

Additional Injection/Series of Injections

- B. Additional injection/series of injections for members who have responded to previous series are considered medically necessary when they meet **all** of the following:
 1. Knee joint osteoarthritis symptoms and pain have reoccurred; **and**
 2. At least **3** months has elapsed since the previous series of injection(s); **and**
 3. The medical record demonstrates a reduction in the dose of NSAIDS (or other analgesics or anti-inflammatory medication) during the 3-month period following the previous series of injections (NOTE: a dose reduction is not required if the member requires these medications for a comorbid medical condition in addition to knee osteoarthritis); **and**
 4. The medical record objectively documents significant improvement in pain and functional capacity as the result of the previous injection(s).

FDA Labeling

Hyalagan	5 injections per series	J7321 billed per dose
Supartz	3 to 5 injections per series	J7321 billed per dose
Visco-3	3 injection per series	J7321 billed per dose
Euflexxa	3 injections per series	J7323 billed per dose
Orthovisc	3 injections per series	J7324 billed per dose
Synvisc	3 injections (16 mg each)	J7325 billed per mg
Synvisc One	1 injection (48 mg)	J7325 billed per mg
Gel One	1 injection	J7326 billed per dose

References:

- 1) Oklahoma Health Care Authority; Policies and Rules, OAC 317:30-3-1 & 30-5-14
- 2) Novitas Solutions LCD (L35427) Hyaluronan Acid Therapies for Osteoarthritis of the Knee, 5/20/2019
- 3) Novitas Solutions Local Coverage Article (A55036) Hyaluronan Acid Therapies for Osteoarthritis of the Knee, 5/20/2019
- 4) Aetna Clinical Policy Bulletins; Number 0179, Viscosupplementation, 4/24/2019
- 5) Euflexxa (sodium hyaluronate) Prescribing information, Ferring Pharmaceuticals, Inc.
- 6) Gel One (cross linked hyaluronate) Prescribing information, Zimmer.
- 7) Hyalgan (sodium hyaluronate) Prescribing information, Fidia Pharma, Inc.
- 8) Orthovisc (high molecular weight hyaluronan) Prescribing information, Anika Therapeutics, Inc.
- 9) Supartz (sodium hyaluronate) Prescribing information, Bioventus, LLC.
- 10) Synvisc (hylan G-F 20) Prescribing information, Genzyme Corporation
- 11) Synvisc One (hylan G-F 20) Prescribing information, Genzyme Corporation
- 12) Visco-3 (sodium hyaluronate) Prescribing information, Bioventus, LLC.