



Intra-articular Injections of HYALURONAN

Policy Number: M-0035

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coverage Guidelines:

Hyalgan

- FDA: Osteoarthritis of knee

Supartz

- FDA: Osteoarthritis of knee

Orthovisc

- FDA: Osteoarthritis of knee

Synvisc

- FDA: Osteoarthritis of knee

Synvisc-One

- FDA: Osteoarthritis of knee

Gel-One

- FDA: Osteoarthritis of knee

Coding Information:

HCPCS Code(s)

J7321	HYALURONAN OR DERIVATIVE, HYALGAN OR SUPARTZ, FOR INTRA-ARTICULAR INJECTION, PER DOSE
J7323	HYALURONAN OR DERIVATIVE, EUFLEXXA, FOR INTRA-ARTICULAR INJECTION, PER DOSE
J7324	HYALURONAN OR DERIVATIVE, ORTHOVISC, FOR INTRA-ARTICULAR INJECTION, PER DOSE
J7325	HYALURONAN OR DERIVATIVE, SYNVISIC OR SYNVISIC-ONE, FOR INTRA-ARTICULAR INJECTION, 1 MG



J7326	HYALURONAN OR DERIVATIVE, GEL-ONE, FOR INTRA-ARTICULAR INJECTION, PER DOSE
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ICD-9 Code(s)

715.16	OSTEOARTHRISIS LOCALIZED PRIMARY INVOLVING LOWER LEG
715.26	OSTEOARTHRISIS LOCALIZED SECONDARY INVOLVING LOWER LEG
715.36	OSTEOARTHRISIS LOCALIZED NOT SPECIFIED WHETHER PRIMARY OR SECONDARY INVOLVING LOWER LEG
715.96	OSTEOARTHRISIS UNSPECIFIED WHETHER GENERALIZED OR LOCALIZED INVOLVING LOWER LEG

Indications and Limitations:

1. The FDA has approved Visco supplementation as a device. Medicare is allowing this nonpharmacologic therapy.

2. This treatment will only be covered for the treatment of pain in osteoarthritis of the knee . It is covered in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen. All other uses will be denied as investigational.

3. There must be radiological evidence to support the diagnosis of osteoarthritis.

4. The following products are covered for injections in the knee:

a. J7321 -Hyaluronan Or Derivative, Hyalgan Or Supartz, For Intra-Articular Injection, Per Dose.

- Hyalgan® - (20mg/2 ml) received FDA approval on 05/28/97. The intra-articular injections are given once a week (one week apart) for a total of five injections.

- Supartz® - (25mg/2.5 ml) received FDA approval on 01/24/01. The intra-articular injections are given once a week for 5 weeks.

b. J7325 - Hyaluronan Or Derivative, Synvisc or Synvisc-One, For Intra-Articular Injection, 1mg Synvisc® - (16mg/2ml) received FDA approval on 08/08/97. The intra-articular injections are given once a week (i.e., at seven-day intervals) for a total of three injections.

Synvisc-One™. It is a single dose injection (48mg/6ml). FDA approved 02/26/09.



c. J7323 - Hyaluronan Or Derivative, Euflexxa, For Intra-Articular Injection, Per Dose Euflexxa® (20mg/2ml) received FDA approval on 10/27/05. The intra-articular injections are given once a week for 3 weeks.

d. J7324- Hyaluronan Or Derivative, Orthovisc, For Intra-Articular Injection, Per Dose Orthovisc® (30mg/2ml) received FDA approval on 02/05/04. The intra-articular injections are administered weekly for 3-4 weeks.

e. J7326-Hyaluronan Or Derivative, Gel-One, For Intra-Articular Injection, per dose Gel-One® (30mg/3ml) received FDA approval on 03/22/11. This is a single dose intra-articular injection.

Documentation Requirements:

Documentation in the patient's medical record must show the patient failed to respond adequately to conservative non-pharmacological therapy (exercise or physical therapy, weight loss if appropriate) and a past history of treatment with analgesics and a radiological exam to support the diagnosis of osteoarthritis.

If subsequent courses of treatment are given, the medical records must support the effectiveness of the prior treatment and must clearly establish reduction of patient symptomatology and medication usage. This documentation must be submitted upon request. Claims submitted without requested supporting evidence in the medical record will be denied as being not medically necessary.

Background:

Purified natural hyaluronates have been approved by the FDA for the treatment of osteoarthritis of the knee in patients who have failed to respond to simple analgesics or conservative nonpharmacologic therapy. Osteoarthritis leads to changes in hyaluronan, a natural substance that helps provide the fluid within the joint with elasticity and viscosity. The goal of visco supplementation is to supplement and restore the natural elastic and viscous properties of the synovial joint fluid. Osteoarthritis (OA) is a common condition affecting the knees. OA is characterized by deterioration and loss of the articular cartilage, subchondral sclerosis and osteophyte formation, and is often accompanied by inflammation of the synovium. This can cause pain and loss of function in the joint. Many treatments have a role in the management of the pain of OA. These include symptomatic pharmacological treatment



with analgesics, non-steroidal anti-inflammatory drugs (NSAID) and intra-articular corticosteroid injections. Muscle strengthening exercises and weight loss has also been helpful in managing osteoarthritis.

Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

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