MEDICAL POLICY STATEMENT		
Original Effective Date	**Next Annual Review Date**	**Last Review / Revision Date**
06/15/2011	**02/14/2017**	**02/14/2016**
Policy Name		**Policy Number**
Hyaluronic Acid Derivative Injection		**SRx-0012**
Policy Type		
☒ **Medical**	☐ **Administrative**	☐ **Payment**

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

A. SUBJECT

Hyaluronic Acid Derivative Injection

- Euflexxa
- Gel-One
- Hyalgan
- Supartz
- Orthovisc
- Synvisc
- Synvisc-One
- Monovisc
- GenVisc 850
- Gel-Syn

B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the Hyaluronic Acid Derivative Injection program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

C. DEFINITIONS

N/A

D. POLICY

I. CareSource will approve the use of hyaluronic acid derivatives, and consider their use as medically necessary when the following criteria have been met for:

A. Osteoarthritis of the knee

Hyaluronic acid derivatives are indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen)

1. Prior Authorization Criteria:

1.1 Intra-articular injection of hyaluronic acid may be indicated when **ALL** of the following are present:

a. Age 50 years or older
b. Diagnosis of Osteoarthritis confirmed by radiological evidence
c. Failure to respond (adequate improvement in pain/function) to or inability to tolerate non-operative treatments, including **ALL** of the following:
   (1) Intra-articular corticosteroid injections
   (2) Lifestyle modifications
   (3) Weight loss for BMI ≥25
   (4) Trial of at least 3 simple analgesic therapy (acetaminophen, NSAIDs, salicylates oral or topical)
   (5) Sufficient trial (e.g. 2 to 3 months) of non-pharmacologic therapies (bracing/orthotics, physical therapy/exercise, weight loss)
d. Knee osteoarthritis, with pain affecting daily activity and quality of life
e. No infection of skin disease at injection site
f. Prescribed by of an Orthopedic Surgeons, Interventional Pain Physicians, Rheumatologists, Physiatrists (PM&R) and all Sports Medicine subspecialties.

1.2 Non-preferred products may be approved if **ALL** above criteria are met **AND** clinical reason is supplied as to why preferred product(s) (formulary) cannot be used

1.3 One (1) additional course of treatment may be approved if **ALL** of the following are met:

a. Documented significant pain relief was achieved with the initial/prior course of treatment
b. Initial/prior course of treatment has been completed for 6 months or longer
c. Patient meets all the criteria for the initial approval

Note: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but not limited to test reports, chart notes from provider's office or hospital admission notes.

Ultrasound guidance for viscosupplement injections is considered experimental and investigational because it has not been established that this approach will improve health outcomes.

All other uses of hyaluronic acid derivative are considered experimental/investigational and may be covered under CareSource's Medical Necessity: Off-Label policy.

Refer to the product package insert for dosing, administration and safety guidelines.

CONDITIONS OF COVERAGE

HCPCS
J7321 Hyalgan / Supartz
J7323 Euflexxa
J7324 Orthovisc
J7325 Synvisc / Synvisc-One
J7326 Gel-One
J7327 Monovisc
J7328 Gel-Syn
J3590 GenVisc 850

CPT
20610- Arthrocentesis, aspiration and /or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance, with permanent recording and reporting

PLACE OF SERVICE

Office, Outpatient
**Preferred place of service is in the provider's office.
Note: CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost effective setting that are supportive of the patient's medical condition and unique needs and condition. The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

AUTHORIZATION PERIOD

Approved initial authorizations are valid for 6 months. **ALL** authorizations are subject to continued eligibility.

E. REVIEW/REVISION HISTORY

Date Issued:	06/15/2011
Date Reviewed:	06/15/2011, 01/15/2013, 02/14/2014, 02/14/2015
Date Revised:	05/15/2013 02/14/2015 – added: all to non-operative failed treatments, Gel-One & J-code & preferred products 02/14/2016 – add sub-specialty; sports med group, age change and 1 additional retreatment

F. REFERENCES

1. Euflexxa [package insert], Parsippany, NJ: Ferring Pharmaceuticals, Inc.; June 2015.
2. Hyalgan [package insert], Parsippany, NJ: Fidia Pharma USA, Inc.; May 2014.
3. Orthovisc [package insert], Woburn, MA.: Anika Therapeutics: January 2010.
4. Supartz [package insert], Durham. NC: Bioventus LLC; June 2012.
5. Synvisc [package insert], Ridgefield, NJ: Genzyme Biosurgery.; September 2014.
6. Synvisc One [package insert], Ridgefield, NJ: Genzyme Biosurgery; January 2010.
7. American Academy of Orthopaedic Surgeons. Treatment of Osteoarthritis of the Knee. Evidence-based guideline 2nd Edition. May 2013. Available at: http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf (December 31, 2015)
8. American College of Rheumatology, Subcommittee on Osteoarthritis Guidelines. Recommendations for the medical management of osteoarthritis of the hip and knee: 2012

update. Arthritis Care & Research 2012; 64(4):465-474. Agency for Healthcare Research and Quality (AHRQ). Three Treatments for Osteoarthritis of the Knee: Evidence Shows Lack of Benefit. Clinician's Guide. March, 2011
9. Chevalier X, Jerosch J, Goupille P, et al. Single, intra-articular treatment with 6 ml hylan G-F 20 in patients with symptomatic primary osteoarthritis of the knee: a randomized, multicentre, double-blind, placebo controlled trial. Ann Rheum Dis. 2010 Jan;69(1):113-9.
10. Goldberg VM, Buckwater MD. Hyaluronans in the treatment of osteoarthritis of the knee: evidence for disease modifying activity. Osteoarthritis and Cartilage March 2005;13(3):216-224.
11. Majeed M. Relationship between serum hyaluronic acid level and disease activity in early rheumatoid arthritis. Ann Rheum Dis September 2004; 63(9): 1166-8.
12. Tascioglu F, Oner C. Efficacy of intra-articular sodium hyaluronate in the treatment of knee osteoarthritis. Clini Rheumatol. 2003;22:112-117.
13. Lo, G H, et al. JAMA. 2003;290:3115-3121. Intra-articular Hyaluronic Acid in Treatment of Knee Osteoarthritis: A Meta- analysis. Retrieved 3/17/2011 from http://jama.ama-assn.org/cgi/reprint/290/23/3115
14. Bellamy N, Campbell J, Robinson V, Gee T, Bourne R, Wells G. Viscosupplementation for the treatment of osteoarthritis of the knee. *Cochrane Database Syst Rev.* 2006;(2):CD005321
15. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. Clin Orthop Relat Res. 2007; 455:113-22
16. MCG 18th edition.
17. Monovisc [package insert], Bedford, MA: Anika Therapeutics, Inc.; December 2013.
18. Gel-One [package insert]. Warsaw, IN: Zimmer, Inc.; May 2011.

The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.

Independent medical review – 5/2011