MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
06/15/2011	02/14/2016	02/14/2015
Policy Name		**Policy Number**
Hyaluronic Acid Derivative Injection		**SRx-0012**

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.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Hyaluronic Acid Derivative Injection

- Euflexxa
- Gel-One
- Hyalgan
- Supartz
- Orthovisc
- Synvisc
- Synvisc-One
- Monovisc

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

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

- Osteoarthritis of the knee

Osteoarthritis

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)

Prior Authorization Criteria:

- Intra-articular injection of hyaluronic acid may be indicated when **ALL** of the following are present:
  - Age 18 years or older
  - Failure to respond to or inability to tolerate non-operative treatments, including **ALL** of the following:
    - Intra-articular corticosteroid injections
    - Lifestyle modifications
      - Weight loss for BMI ≥25
    - Non-narcotic analgesics (e.g., tramadol)
    - NSAIDs oral or topical
  - Knee osteoarthritis, with pain affecting daily activity and quality of life
  - No infection of skin disease at injection site
  - Prescribed by or under the direction of an orthopedist
- Non-preferred products (Euflexxa, Synvisc, Synvisc One, Hyalgan, Orthovisc or Monovisc) may be approved if **ALL** above criteria are met **AND** clinical reason is supplied as to why Supartz or Gel-One cannot be used
- Repeated course(s) of treatment may be approved if **ALL** of the following are met:
  - Significant pain relief was achieved with the initial/prior course of treatment
  - Initial/prior course of treatment has been completed for 6 months or longer

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.

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

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

For Medicare Plan members, refer to the CareSource policy and Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE

HCPCS	J7321	Hyalgan / Supartz
	J7323	Euflexxa
	J7324	Orthovisc
	J7325	Synvisc / Synvisc-One
	J7326	Gel-One
	J7327	Monovisc

CPT

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:	01/15/2013
	02/14/2014
	02/14/2015 – added: all to non-operative failed treatments, Gel-One & J-code & preferred products

F. REFERENCES

1. Euflexxa [package insert], Suffern, NY: Ferring Pharmaceuticals, Inc.; May 2006.
2. Hyalgan [package insert], Bridgewater, NJ.: Sanofi-Aventis: July 2001.
3. Orthovisc [package insert], Woburn, MA.: Anika Therapeutics: January 2010. Supartz [package insert], Memphis, TN.: Smith & Nephew Ortho; January 2007. Synvisc [package insert], Cambridge, MA.: Genzyme Corp.; December 2006. Synvisc One [package insert], Cambridge, MA.: Genzyme Corp.; December 2006
4. American Academy of Orthopaedic Surgeons Clinical Practice Guideline on the Treatment of Osteoarthritis of the Knee (Non-Arthroplasty). Rosemont (IL): American Academy of Orthopaedic Surgeons (AAOS); 2008. Available at: http://www.aaos.org/research/guidelines/OAKguideline.pdf. (March 28, 2011)
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13. Divine JG; Zazulak BT; Hewett TE. Viscosupplementation for knee osteoarthritis: a systematic review. Clin Orthop Relat Res. 2007; 455:113-22
14. MCG 18th edition.
15. Monovisc [package insert], Bedford, MA: Anika Therapeutics, Inc.; December 2013.

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