Hyaluronate Products
Durolane (hyaluronic acid)
Euflexxa® (1% sodium hyaluronate)
Gel-One® (cross-linked hyaluronate)
Gelsyn-3 (sodium hyaluronate 0.84%)
Genvisc 850 (sodium hyaluronate)
Hyalgan® (sodium hyaluronate)
Hymovis (high molecular weight viscoelastic hyaluronan)
Monovisc™ (high molecular weight hyaluronan)
Orthovisc® (high molecular weight hyaluronan)
Supartz® (sodium hyaluronate)
Supartz FX ® (sodium hyaluronate)
Synvisc® (hylan G-F 20)
Synvisc One® (hylan G-F 20)
Visco-3® (sodium hyaluronate)

Polices of Business:
HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 07/20/2018

Policy

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
• Treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (eg, acetaminophen).

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
• Prescribers must provide the names of previous pharmacologic treatments that were tried and failed (e.g., acetaminophen, nonsteroidal anti-inflammatory drugs [NSAIDs], cyclooxygenase-2 [COX2] inhibitor, tramadol, or intra-articular corticosteroid injection) or the intolerance or contraindication to such treatments
• For continuation of therapy only:
C. CRITERIA FOR APPROVAL

1. Osteoarthritis of the knee
   a. Authorization of 1 course (See Section F – Appendix A) may be granted to members who meet ALL of the following criteria:
      i. Member had an inadequate response to 6 months of conservative therapy
      ii. Member had an inadequate response to non-drug therapy (exercise program and strength training, and/or physical therapy, counseling regarding weight management if appropriate)
      iii. Member had an inadequate response to treatment with an oral/topical NSAID or a COX2 inhibitor OR has a contraindication or history of intolerance to NSAIDs and/or COX2 inhibitors (See Section F – Appendix B)
      iv. Member had an inadequate response to an intra-articular corticosteroid injection OR has a contraindication or history of intolerance to intra-articular corticosteroid injections (See Section F – Appendix B)

D. CONTINUATION OF THERAPY

1. No previous authorization/precertification:
   All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
2. Reauthorization:
   Authorization of 1 course (See Section F – Appendix A) may be granted to members who have previously received a course of treatment with an intra-articular hyaluronate product for the knee joint and was previously approved by HMSA/CVS and there is evidence of benefit from therapy and when ALL of the following criteria are met:
   1. The start of the next treatment course with the requested product is planned to be at least 6 months after the start of the last course of treatment.
   2. Member must have experienced pain relief from the previous course of treatment.

E. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES

Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

G. Program Exception – Medicare Advantage

- Effective May 15, 2018, hyaluronate acid injectable medication for HMSA Medicare Advantage members must be billed by a contracted Medicare Part B provider. This means a pharmacy cannot bill for hyaluronate acid injections for HMSA Medicare Advantage members.
HMSA is making this change because Medicare requires that Part B injections administered in an office setting be billed by a contracted Medicare Part B provider as a medical claim. Please go to cms.gov and refer to CMS Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C, for more information.

H. APPENDICES

Appendix A. Course of Therapy – Intra-Articular Hyaluronate Products

- Euflexxa: 3 injections
- Gel-One: 1 injection
- Gelsyn-3: 3 injections
- GenVisc 850: 3 to 5 injections
- Hyalgan: 3 to 5 injections
- Hymovis: 2 injections
- Monovisc: 1 injection
- Orthovisc: 3 or 4 injections
- Supartz: 3 to 5 injections
- Supartz FX: 3 to 5 injections
- Synvisc One: 1 injection
- Synvisc: 3 injections
- Visco-3: 3 injections

Appendix B. Examples of Contraindications to NSAIDS/COX-2 Inhibitor and Intra-Articular Corticosteroids

- History of intolerance or adverse event
- Hypersensitivity
- Significant drug interaction

I. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

J. REFERENCES

**Document History**

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