POLICY AND PROCEDURE

DEPARTMENT: Medical Management	**DOCUMENT NAME:** Viscosupplementation of the Knee for Osteoarthritis
PAGE: 1 of 8	**REPLACES DOCUMENT:**
APPROVED DATE: 12/2014	**RETIRED:**
EFFECTIVE DATE: 12/2014	**REVIEWED/REVISED** 12/2015; 11/2016; 8/2017; 12/2017
PRODUCT TYPE: All	**REFERENCE NUMBER:** WA.UM.26

SCOPE:
Coordinated Care Health Plan

SUBJECT:
The intent of the criteria is to ensure that patients follow selection elements established by medical policy for the pharmacologic treatment for osteoarthritis (OA) of the knee.

- Euflexxa® (1% sodium hyaluronate)
- Gel-One® (cross-linked hyaluronate)
- Hyalgan® (sodium hyaluronate)
- Orthovisc® (high molecular weight hyaluronan)
- Monovisc® (high molecular weight hyaluronan)
- Supartz® (sodium hyaluronate)
- Synvisc® (hylan G-F 20)
- Synvisc One® (hylan G-F 20)
- Hymovis
- GencVisc 850

Policy/Criteria

I. It is the policy of Coordinated Care in accordance with the Health Care Authority's HealthTechnology Assessment that viscosupplementation of the knee is **medically necessary** for members meeting the following criteria:

A. *Initiation* of viscosupplementation when all of the following are met:

1. Diagnosis of osteoarthritis of the knee supported by radiographic imaging; and
2. Inadequate response to physical therapy or a physician directed exercise program; and
3. Failure, contraindication, or intolerance to one of the following (a or b):
    a. Oral nonsteroidal anti-inflammatory drug (NSAID) at continuous therapeutic (prescription strength) dosing for ≥ 2 weeks;
    b. If member is ≥ 75 years old or unable to take oral NSAID, topical NSAID for ≥ 2 weeks;
    and
4. Member has none of the following contraindications:
    a. Hypersensitivity to hyaluronate preparations;

   b. Infections or skin diseases in the area of the injection site or knee joint;
   c. If Hymovis, Monovisc or Orthovisc, hypersensitivity to gram positive bacterial proteins.
5. Experienced an inadequate response, or no longer responding to, intraarticular glucocorticoids, or has contraindications to intraarticular glucocorticoids.

II. Continued Approval

A. Osteoarthritis of the Knee (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member is responding positively to therapy;
3. It has been at least 4 months since last injection. No more than two injections per year.
4. Member has none of the following reasons to discontinue:
   a. Hypersensitivity to hyaluronate preparations;
   b. Infections or skin diseases in the area of the injection site or knee joint;
   c. If Hymovis, Monovisc or Orthovisc, hypersensitivity to gram positive bacterial proteins.

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

Background

Healthy cartilage allows bones to glide over one another and absorbs energy from the shock of physical movement. In patients with OA, the surface layer of cartilage breaks down and wears away. The bones under the cartilage begin to rub together which causes pain, swelling, and loss of motion of the joint. Although there is no cure for OA, individualized treatment can reduce pain, maintain and/or improve joint mobility, and limit functional impairment.[7] Hyaluronate injections are FDA approved for knee OA.[1-6,9,11] The American College of Rheumatology (ACR) guidelines conditionally recommend initial treatment with acetaminophen, oral and topical nonselective nonsteroidal anti-inflammatory drugs (NSAIDs), tramadol, and intraarticular corticosteroids for knee OA.[10] In cases where there is an

inadequate response to initial therapy, the ACR guidelines conditionally recommend intraarticular hyaluronate injections, duloxetine, and opioids.[10] Although the pain-relieving effect of hyaluronate injections is not immediate, it may last for several months.[8]

Appendices

Appendix A: Abbreviation key

ADL: activity of daily living
APAP: Acetaminophen
NSAID: Non-steroidal anti-inflammatory drug
OA: Osteoarthritis

Appendix B: Safety

Appendix B-1: Clinical Reasons to Avoid NSAID Therapy[7]

- Acetaminophen
  - Pre-existing renal disease
  - Liver disease
  - Chronic alcohol abuse
  - Anticoagulation therapy
- NSAID
  - Allergy
  - Gastrointestinal intolerance despite use of enteric-coated tablets
  - At high risk for gastrointestinal bleeding, for example:
    - Age ≥ 65
    - Co-morbid medical conditions
    - Oral glucocorticoids
    - History of upper gastrointestinal bleeding
    - Anticoagulant
- History of peptic ulcer disease
  - Co-morbid medical conditions
    - Renal disease
    - Congestive heart failure
    - Cirrhosis
    - Volume depletion
    - Diuretic use
    - Elderly
  - Adverse reactions to NSAIDs
    - Rash or allergic reaction
    - Increase in blood pressure
    - Edema

Appendix B-2: Contraindications to Intraarticular Hyaluronic Acid Agents[1-6,9,11]

- Do not inject in the knees of patients with infections or skin diseases in the area of the injection site or joint to reduce the potential for developing septic arthritis.

- Hyalgan, Orthovisc, Supartz, Synvisc, and Synvisc One should be used with caution in patients who are allergic to avian proteins, feathers, or eggs
- Monovisc should not be administered to patients with known hypersensitivity to gram positive bacterial proteins.

References

1. Euflexxa Prescribing Information. Parsippany, NJ: Ferring Pharmaceuticals, Inc. June 2015. Available at http://www.euflexxa.com/sites/default/files/full_prescribing_information.pdf. Accessed August 23, 2016.
2. Gel-One Prescribing Information. Warsaw, IN: Zimmer; May 2011. Available at http://www.zimmer.com/content/dam/zimmer-web/documents/en-US/pdf/medical-professionals/biologics-sports-medicine/Gel-One-Pkg-Insert-Final.pdf. Accessed August 23, 2016.
3. Hyalgan Prescribing Information. Parsippany, NJ: Fidia Pharmas USA, Inc.; May 2014. Available at http://hyalgan.com/wp-content/uploads/2016/02/hyalgan_pi.pdf. Accessed August 23, 2016.
4. Monovisc Prescribing Information. Bedford, MA: Anika Therapeutics, Inc. Received from distributor, DePuy Synthes Mitek Sports Medicine, August 23, 2016.
5. Orthovisc Prescribing Information. Woburn, MA: Anika Therapeutics, Inc.; June 2005. Received from distributor, DePuy Synthes Mitek Sports Medicine, August 23, 2016.
6. Supartz Prescribing Information. Durhan, NC: Bioventus, LLC; April 2015. Available at http://www.supartzfx.com//wp-content/uploads/2015/07/SUPARTZ_FX_Package_Insert.pdf. Accessed August 23, 2016.
7. Synvisc Prescribing Information. Ridgefield, NJ: Genzyme Biosurgery; September 2014. Available at http://products.sanofi.us/synvisc/synvisc.html. Accessed August 23, 2016.
8. Synvisc One Prescribing Information. Ridgefield, NJ: Genzyme Biosurgery; September 2014. Available at http://products.sanofi.us/synviscone/synviscone.html. Accessed August 23, 2016.
9. Hymovis Prescribing Information. Parsippany, NJ: Fidia Pharma USA, Inc.; October 2015. Available at

http://www.hymovis.com/pdf/HYMOVIS%20PI.pdf. Accessed August 25, 2016.

10. GenVisc 850 Prescribing Information. Doylestown, PA: Orthogen Rx, Inc.; October 2015. Available at http://genvisc850.com/images/genvisc-850-full-prescribing-information.pdf. Accessed August 25, 2016.
11. Tramadol Drug Monograph. Clinical Pharmacology. Accessed October 2016. http://www.clinicalpharmacology-ip.com
12. Strand V, Baraf HS, Lavin PT, et al. Effectiveness and safety of a multicenter extension and retreatment trial of Gel-200 in patients with knee osteoarthritis. *Cartilage.* 2012;3(4):297-304.
13. Sun SF, Hsu CW, Hwang CW, et al. Hyaluronate improves pain, physical function and balance in the geriatric osteoarthritic knee: A 6-month follow-up study using clinical tests. *Osteoarthritis Cartilage.* 2006;14:696-701.
14. Brown GA. American Academy of Orthopaedic Surgeons clinical practice guidelines: Treatment of osteoarthritis of the knee: Evidence-based guideline, 2nd edition. *J Am Acad Orthop Surg.* September 2013;21(9):577-9. doi: 10.5435/JAAOS-21-09-577.
15. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res.* 2012;64(4):465-474.
16. Bannuru RR, Osani M, Vaysbrot EE, McAlindon TE. Comparative safety profile of hyaluronic acid products for knee osteoarthritis: a systematic review and network meta-analysis. Osteoarthritis Cartilage. August 2, 2016. pii: S1063-4584(16)30196-0. doi: 10.1016/j.joca.2016.07.010. [Epub ahead of print]
17. Hyaluronate derivatives: Drug Information. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed August 25, 2016.
18. Tramadol: Drug Information. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed October 17, 2016.
19. Kalunian KC. Initial pharmacologic therapy of osteoarthritis. In: UpToDate (Lexicomp), Waltham, MA: Walters Kluwer Health; 2016. Available at UpToDate.com. Accessed October 17, 2016.
20. Rannou F, Peletier JP, Martel-Pelletier J. Efficacy and safety of topical NSAIDs in the management of osteoarthritis: Evidence from real-life setting trials and surveys. *Semin Arthritis Rheum.* 2016; 45:S18-S21.

21. McAlindon TE, Bannuru RR, Sullivan MC, at al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014; 22:363-388.
22. Nelson AE, Allen KD, Golightly YM, et al. A systematic review of recommendations and guidelines for the management of osteoarthritis: The chronic osteoarthritis management initiative of the U.S. Bone and Joint Initiative. *Semin Arthritis Rheum*. 2014; 43:701-712.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective

date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Revision Log	**Date**
Updated criteria to include failure of physical therapy or home exercise program	12/1/2015

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Annual review, updated HTA link no changes to HTA criteria. Converted policy to new template. Added two new products approved in 2015: Hymovis and GenVisc850. Approval duration edited to one treatment course every 4 months rather than every 13 weeks. Removed "interference with ADLs" requirement. Edited step therapy to require an inadequate response to all of the following drugs: a two-week trial of oral NSAIDs if <75 years of age or unable to use oral NSAID, topical NSAID for ≥ 2 weeks, tramadol if no opioid abuse or dependence. Removed acetaminophen requirement. Updated references	11/23/2016
Removed requirement for Tramadol to align with corporate policy for Hyaluronate Derivatives	8/25/2017
Added criteria for treatment with a glucocorticoid for initial treatment approval.	12/4/2017