Hyaluronic Acid Derivatives:
Euflexxa™, Synvisc™, Synvisc-One™
(Intra-articular)

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I. Important Note:

a. **Medica ONLY covers Synvisc/Synvisc-One and Euflexxa (preferred). All other Hyaluronic Acid Derivatives will not be covered. This requirement is applicable to non-Medicare requests only.**

II. Length of Authorization

Coverage will be provided for six months and may be renewed.

III. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Drug	Injections per knee	Injections both knees	Days Supply
Euflexxa 20 mg/2 mL injection	3	6	180
Synvisc 16 mg/2 mL injection	3	6	180
Synvisc-One 48 mg/6 mL injection	1	2	180

B. Max Units (per dose and over time) [HCPCS Unit]:*

Drug	HCPCS	1 Billable Unit (BU)	BU per Admin	No. Admins (per knee per 180 days)	Max Units (per 180 days)*
Euflexxa	J7323	1 dose	1	3	6
Synvisc	J7325	1 mg	16	3	96

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Synvisc-One	J7325	1 mg	48	1	96

*Max units are based on administration to both knees

IV. Initial Approval Criteria

Coverage is provided in the following conditions:

Universal Criteria [1-15,23-25]

- Patient does not have any conditions which would preclude intra-articular injections (e.g., active joint infection, unstable joint, bleeding disorders, etc.); **AND**
- Patient has not received therapy with intra-articular long-acting corticosteroid type drugs (i.e. Zilretta, etc.) within the previous 6 months of therapy; **AND**

Osteoarthritis of the knee †

- Documented symptomatic osteoarthritis of the knee; **AND**
- The patient has had a trial and failure to BOTH of the following conservative methods which have not resulted in functional improvement after at least three (3) months:
    - Non-Pharmacologic (i.e., physical, psychosocial, or mind-body approach [e.g., exercise-land based or aquatic, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane, etc.]); **AND**
    - Pharmacologic Approach (e.g., topical NSAIDs, oral NSAIDs with or without oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine, etc.); **AND**
- The patient has failed to adequately respond to aspiration and injection of intra-articular steroids; **AND**
- The patient reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)

† FDA Approved Indication(s)

V. Renewal Criteria [1-15,23-25]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section IV; **AND**
- Disease response with treatment as defined by improvement in signs and symptoms of pain and a stabilization or improvement in functional capacity during the 6-month period following the previous series of injections as evidenced by objective measures; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe joint swelling and pain, severe infections, anaphylactic or anaphylactoid reactions, etc.

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VI. Dosage/Administration (per knee per 180 days)

Drug	Dose
Euflexxa	20 mg intra-articularly once weekly x 3 administrations
Synvisc	16 mg intra-articularly once weekly x 3 administrations
Synvisc-One	48 mg intra-articularly x 1 administration

VII. Billing Code/Availability Information

HCPCS Code & NDC:

Drug	HCPCS Code	1 Billable Unit	Dose per Injection	Injections (per knee per 180 days)	NDC
Euflexxa	J7323	1 dose	20 mg/2 mL	3	55566-4100-xx
Synvisc	J7325	1 mg	16 mg/2 mL	3	58468-0090-xx
Synvisc-One	J7325	1 mg	48 mg/6 mL	1	58468-0090-xx

VIII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of knee, unspecified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD):

Jurisdiction(s): N	**NCD/LCA/LCD Document (s):** A57256
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57256&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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Jurisdiction(s): 6, K	NCD/LCA/LCD Document (s): A52420
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52420&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): H, L	NCD/LCA/LCD Document (s): A55036
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a55036&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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