

Hyaluronic Acid Derivatives:

Durolane[®], Euflexxa[™], Gel-One[®], GelSyn-3[™], GenVisc 850[®], Hyalgan[™], Hymovis[®], Monovisc[®], Orthovisc[™], Supartz/Supartz FX[™], Synjoynt[™], Synvisc[™], & Synvisc-One[™], TriVisc[™], Visco-3[™] (Intra-articular)

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

Drug	Injections per knee	Injections both knees	Days Supply
Euflexxa 20 mg/2 mL injection	3	6	180
Durolane 60 mg/3 mL injection	1	2	180
Gel-One 30 mg/3 mL injection	1	2	180
GelSyn-3 16.8 mg/2 mL injection	3	6	180
GenVisc 850 25mg/3 ml injection	5	10	180
Hyalgan 20 mg/2 mL injection	5	10	180
Hymovis 24 mg/3 mL injection	2	4	180
Monovisc 88 mg/4 mL injection	1	2	180
Orthovisc 30 mg/2 mL injection	4	8	180
Supartz 25 mg/2.5 mL injection	5	10	180
Supartz FX 25 mg/2.5 mL injection	5	10	180
Synjoynt 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
Trivisc 25 mg/2.5mL injection	3	6	180

Visco-3	3	6	180
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B. Max Units (per dose and over time) [Medical Benefit]:*

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
Durolane	J7318	1 mg	60	1	120
Gel-One	J7326	1 dose	1	1	2
GelSyn-3	J7328	0.1 mg	168	3	1008
GenVisc 850	J7320	1 mg	25	5	250
Hyalgan; Supartz; Supartz FX	J7321	1 dose	1	5	10
Hymovis	J7322	1 mg	24	2	96
Monovisc	J7327	1 dose	1	1	2
Orthovisc	J7324	1 dose	1	4	8
Synjoynt	J3490	1 dose	1	3	6
Synvisc	J7325	1 mg	16	3	96
Synvisc-One	J7325	1 mg	48	1	96
Trivisc	J7329	1 mg	25	3	150
VISCO-3	J7321	1 dose	1	3	6

*Max units are based on administration to both knees

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Osteoarthritis of the knee †

- Documented symptomatic osteoarthritis of the knee; **AND**
- Trial and failure of conservative therapy (including physical therapy, pharmacotherapy [e.g., non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen (up to 1 g 4 times/day) and/or topical capsaicin cream]) has been attempted and has not resulted in functional improvement after at least 3 months; **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); **AND**
- There are no contraindications to the injections (e.g., active joint infection, bleeding disorder); **AND**

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| <ul style="list-style-type: none"> • Patient has tried and failed to respond or tolerate Euflexxa and Synvisc-One in the same knee joint previously |
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† FDA Approved Indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- The medical record demonstrates a reduction in the dose of NSAIDS (or other analgesics or anti-inflammatory medication) during the 6-month period following the previous series of injections; **AND**
- The medical record objectively documents significant improvement in pain and functional capacity as the result of the previous injections; **AND**
- Absence of unacceptable toxicity from the previous injections. Examples of unacceptable toxicity include: severe joint swelling and pain, severe infections, anaphylactic or anaphylactoid reactions, etc.

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

Drug	Dose
Euflexxa	20 mg intra-articularly once weekly x 3 administrations
Durolane	60 mg intra-articularly x 1 administration
Gel-One	30 mg intra-articularly x 1 administration
GelSyn-3	16.8 mg intra-articularly once weekly x 3 administrations
GenVisc 850	25 mg intra-articularly once weekly x 5 administrations
Hyalgan	20 mg intra-articularly once weekly x 5 administrations
Hymovis	24 mg intra-articularly once weekly x 2 administrations
Monovisc	88 mg intra-articularly x 1 administration
Orthovisc	30 mg intra-articularly once weekly x 4 administrations
Supartz/Supartz FX	25 mg intra-articularly once weekly x 5 administrations
Synjoynt	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
Trivisc	25 mg intra-articular once weekly x 3 administrations
Visco-3	25 mg intra-articularly once weekly x 3 administrations

VI. Billing Code/Availability Information

Jcode & NDC:

Drug	Jcode	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

Durolane	J7318 (effective 1/1/19), J3490 or C9465 (inactive 1/1/19)	1 mg	60 mg/3 mL	1	89130-2020-xx
Gel-One	J7326	1 dose	30 mg/3 mL	1	87541-0300-xx
GelSyn-3	J7328	0.1 mg	16.8 mg/2 mL	3	89130-3111-xx
GenVisc 850	J7320	1 mg	25mg/2.5 ml	5	50653-0006-xx
Hyalgan	J7321	1 dose	20 mg/2 mL	5	89122-0724-xx
Hymovis	J7322	1 mg	24 mg/3 mL	2	89122-0496-xx
Monovisc	J7327	1 dose	88 mg/4 mL	1	59676-0820-xx
Orthovisc	J7324	1 dose	30 mg/2 mL	4	59676-0360-xx
Supartz	J7321	1 dose	25 mg/2.5 mL	5	89130-5555-xx
Supartz FX	J7321	1 dose	25 mg/2.5 mL	5	89130-4444-xx
Synjoynt	J3490	1 dose	20 mg/2 ml	3	N/A
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
Trivisc	J7329 (effective 1/1/19), J3490	1 mg	25 mg/2.5 ml	3	50563-0006-xx
VISCO-3	J7321	1 dose	25mg/2.5 mL	3	87541-0301-xx

VII. References

1. Supartz/Supartz FX [package insert]. Durham, NC; Bioventus LLC; April 2015. Accessed April 2018.
2. Hyalgan [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; May 2014. Accessed April 2018.
3. Euflexxa [package insert]. Parsippany, NJ; Ferring Pharmaceuticals; July 2016. Accessed April 2018.
4. Synvisc/Synvisc-One [package insert]. Ridgefield, NJ; Genzyme Biosurgery; September 2014. Accessed April 2018.
5. Orthovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; September 2014. Accessed April 2018.
6. Gel-One [package insert]. Warsaw, IN; Zimmer; May 2011. Accessed April 2018.
7. Monovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; February 2014. Accessed April 2018.
8. GelSyn-3 [package insert]. Durham, NC; Bioventus LLC; February 2016; Accessed April 2018.

9. GenVisc 850 [package insert]. Doylestown, PA; OrthogenRx, Inc; September 2015; Accessed April 2018.
10. Hymovis [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; October 2015. Accessed April 2018.
11. Visco-3 [package insert]. Durham, NC; Bioventus LLC; December 2015. Accessed April 2018.
12. Durolane [package insert]. Durham, NC; Bioventus LLC; September 2017. Accessed April 2018.
13. Trivisc [package insert]. Doylestown, PA; OrthogenRx, Inc; November 2017. Accessed April 2018.
14. Synjoynt [packager insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc; June 2018. Accessed June 2018.
15. Hochberg MC, Altman RD, April KT, et al. 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 (Hoboken)*. 2012 Apr;64(4):465-74.
16. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014 Mar;22(3):363-88. doi: 10.1016/j.joca.2014.01.003. Epub 2014 Jan 24.
17. Brown GA. AAOS clinical practice guideline: treatment of osteoarthritis of the knee: evidence-based guideline, 2nd edition. *J Am Acad Orthop Surg*. 2013 Sep;21(9):577-9. doi: 10.5435/JAAOS-21-09-577.
18. Cooper C, Rannou F, Richette P, et al. Use of intra-articular hyaluronic acid in the management of knee osteoarthritis in clinical practice. *Arthritis Care Res (Hoboken)*. 2017 Jan 24.
19. Bhadra AK, Altman R, Dasa V, et al. Appropriate use criteria for hyaluronic acid in the treatment of knee osteoarthritis in the United States. *Cartilage*. 2016 Aug 10.
20. National Institute for Health and Care Excellence. NICE 2014. Osteoarthritis-Care and management in adults. Published Feb 2014. Clinical guideline CG177. <https://www.nice.org.uk/guidance/cg177/evidence/full-guideline-pdf-191761309>. Accessed November 2017.
21. Wisconsin Physicians Service Insurance Corporation. Local Coverage Determination (LCD): Intra-articular Injections of Hyaluronan (L34525). Centers for Medicare & Medicaid Services, Inc. Updated on 3/20/2018 with effective date 04/01/2018. Accessed June 2018.
22. Novitas Solutions, Inc. Local Coverage Determination (LCD): Hyaluronan Acid Therapies for Osteoarthritis of the Knee (L35427). Centers for Medicare & Medicaid Services, Inc. Updated on 01/19/2018 with effective date 1/1/2018. Accessed June 2018.
23. Palmetto GBA. Local Coverage Determination (LCD): Hyaluronate Polymers (L33432). Centers for Medicare & Medicaid Services, Inc. Updated on 04/03/2018 with effective date 04/12/2018. Accessed June 2018.

24. First Coast Service Options, Inc. Local Coverage Determination (LCD): Viscosupplementation Therapy for Knee (L33767). Centers for Medicare & Medicaid Services, Inc. Updated on 02/02/2018 with effective date 02/08/2018. Accessed June 2018.
25. National Government Services, Inc. Local Coverage Article: Hyaluronans (e.g. Hyalgan®, Supartz®, Euflexxa™, Synvisc®, Synvisc-One™, Orthovisc®, Gel-One®), Intra-articular Injections of - Related to LCD L33394 (A52420). Centers for Medicare & Medicaid Services, Inc. Updated on 5/4/2018 with effective date 4/1/2018. Accessed June 2018.
26. Novitas Solutions, Inc. Local Coverage Article: HYALURONAN Acid Therapies for Osteoarthritis of the Knee- Related to LCD L35427 (A55036). Centers for Medicare & Medicaid Services, Inc. Updated on 1/19/2018 with effective date 1/1/2018. Accessed June 2018.

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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

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

Jurisdiction(s): 5, 8	NCD/LCD Document (s): L34525
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34525&bc=gAAAAAAAAAAAAAA==	
Jurisdiction(s): L, H	NCD/LCD Document (s): L35427

<https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35427&bc=gAAAAAAAAAAAAAA>==

Jurisdiction(s): J, M

NCD/LCD Document (s): L33432

<https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33432&bc=gAAAAAAAAAAAAAA>==

Jurisdiction(s): N

NCD/LCD Document (s): L33767

<https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33767&bc=gAAAAAAAAAAAAAA>==

Jurisdiction(s): 6, K

NCD/LCD Document (s): A52420

<https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52420&bc=gAAAAAAAAAAAAAA>==

Jurisdiction(s): H, L

NCD/LCD Document (s): A55036

<https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A55036&bc=gAAAAAAAAAAAAAA>==

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