Hyaluronic Acid Derivatives:
Durolane®, Euflexxa™, Gel-One®, GelSyn-3™, GenVisc 850®, Hyalgan™, Hymovis®, Monovisc®, Orthovisc™, Supartz/Supartz FX™, Synojoynt, Synvisc™, Synvisc-One™, Triluron™, TriVisc™, & VISCO-3™
(Intra-articular)

Document Number: IC-0061

Last Review Date: 10/03/2023

Date of Origin: 01/01/2012

Dates Reviewed: 03/2012, 06/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 06/2015, 12/2015, 03/2016, 06/2016, 09/2016, 12/2016, 03/2017, 06/2017, 09/2017, 11/2017, 12/2017, 03/2018, 06/2018, 07/2018, 10/2018, 07/2019, 10/2019, 03/2020, 10/2020, 04/2021, 10/2021, 02/2022, 10/2022, 10/2023

- Coverage is provided for Synvisc, Synvisc-One, and Euflexxa
- All other products are NOT covered.

I. Length of Authorization

Coverage will be provided for 6 months initially and may be renewed annually thereafter.

II. Dosing Limits

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

Drug	Injections per knee	Injections both knees	Days Supply
Durolane 60 mg/3 mL injection	1	2	180
Euflexxa 20 mg/2 mL injection	3	6	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
Synojoynt 20 mg/2 mL	3	6	180
Synvisc 16 mg/2 mL injection	3	6	180
Synvisc-One 48 mg/6 mL injection	1	2	180
Triluron 20 mg/2 mL injection	3	6	180
Trivisc 25 mg/2.5mL injection	3	6	180
VISCO-3 25 mg/2.5 mL injection	3	6	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)*
Durolane	J7318	1 mg	60	1	120
Euflexxa	J7323	1 dose	1	3	6
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
Synojoynt	J7331	1 mg	20	3	120
Synvisc	J7325	1 mg	16	3	96
Synvisc-One	J7325	1 mg	48	1	96
Triluron	J7332	1 mg	20	3	120
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:

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 † [1-15,23-25,27-29]

- Patient has a radiographically* confirmed diagnosis of 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)

**Note: Imaging is not required to make the diagnosis in patients with a typical presentation of OA*[27]

† FDA Approved Indication(s)

IV. Renewal Criteria [1-15,23-25,27-29]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **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: severe joint swelling and pain, severe infections, anaphylactic or anaphylactoid reactions, etc.

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

Drug	Dose
Durolane	60 mg intra-articularly x 1 administration
Euflexxa	20 mg intra-articularly once weekly x 3 administrations
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
Synojoynt	20 mg intra-articularly once weekly x 3 administrations
Supartz/Supartz FX	25 mg intra-articularly once weekly x 5 administrations
Synvisc	16 mg intra-articularly once weekly x 3 administrations
Synvisc-One	48 mg intra-articularly x 1 administration
Triluron	20 mg intra-articularly once weekly x 3 administrations
Trivisc	25 mg intra-articularly once weekly x 3 administrations
VISCO-3	25 mg intra-articularly once weekly x 3 administrations

VI. Billing Code/Availability Information

HCPCS Code & NDC:

Drug	HCPCS Code	1 Billable Unit	Dose per Injection	Injections (per knee per 180 days)	NDC
Durolane	J7318	1 mg	60 mg/3 mL	1	89130-2020-xx
Euflexxa	J7323	1 dose	20 mg/2 mL	3	55566-4100-xx
Gel-One	J7326	1 dose	30 mg/3 mL	1	50016-0957-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
Synojoynt	J7331	1 mg	20 mg/2 mL	3	82197-0721-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
Triluron	J7332	1 mg	20 mg/2 mL	3	89122-0879-xx
Trivisc	J7329	1 mg	25 mg/2.5 mL	3	50563-0006-xx
Visco-3	J7321	1 dose	25mg/2.5 mL	3	50016-0957-xx

VII. References

1. Supartz/Supartz FX [package insert]. Durham, NC; Bioventus LLC; April 2015. Accessed August 2023.

2. Hyalgan [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; August 2017. Accessed August 2023.
3. Euflexxa [package insert]. Parsippany, NJ; Ferring Pharmaceuticals; July 2016. Accessed August 2023.
4. Synvisc/Synvisc-One [package insert]. Ridgefield, NJ; Genzyme Biosurgery; May 2023. Accessed August 2023.
5. Orthovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; October 2020. Accessed August 2023.
6. Gel-One [package insert]. Warsaw, IN; Zimmer; May 2011. Accessed August 2023.
7. Monovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; February 2014. Accessed August 2023.
8. GelSyn-3 [package insert]. Durham, NC; Bioventus LLC; December 2017; Accessed August 2023.
9. GenVisc 850 [package insert]. Doylestown, PA; OrthogenRx, Inc; November 2019; Accessed August 2023.
10. Hymovis [package insert]. Florham Park, NJ; Fidia Pharma USA Inc.; September 2017. Accessed August 2023.
11. VISCO-3 [package insert]. Durham, NC; Bioventus LLC; December 2015. Accessed August 2023.
12. Durolane [package insert]. Durham, NC; Bioventus LLC; September 2017. Accessed August 2023.
13. Trivisc [package insert]. Doylestown, PA; OrthogenRx, Inc; December 2017. Accessed August 2023.
14. Triluron [package insert]. Florham Park, NJ; Fidia Pharma USA Inc.; July 2019. Accessed August 2023.
15. Synojoynt [package insert]. Naples, FL; Arthrex, Inc.; January 2022. Accessed August 2023.
16. 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.
17. 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.
18. 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.
19. 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.
20. 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.

21. 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 August 2018.
22. Strand V, Baraf H, Lavin P, et. al. Effectiveness and Safety of a Multicenter Extension and Retreatment Trial of Gel-200 in Patients with Knee Osteoarthritis. Cartilage. 2012 Oct; 3(4): 297–304.
23. Gandek B. Measurement properties of the Western Ontario and McMaster Universities Osteoarthritis Index: a systematic review. Arthritis Care Res (Hoboken). 2015 Feb;67(2):216-29. doi: 10.1002/acr.22415..
24. Bannaru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage. 2019 Jun;27(11):1578-1589. DOI:https://doi.org/10.1016/j.joca.2019.06.011.
25. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee Arthritis Rheumatol. 2020 Feb;72(2):220-233. doi: 10.1002/art.41142. Epub 2020 Jan 6.
26. Sakellariou G, Conaghan PG, Zhang W, et al. EULAR recommendations for the use of imaging in the clinical management of peripheral joint osteoarthritis. Annals of the Rheumatic Diseases 2017;76:1484-1494.
27. National Institute for Health and Care Excellence. NICE 2022. Osteoarthritis in over 16s: diagnosis and management. Published Oct 2022. Clinical guideline NG226. https://www.nice.org.uk/guidance/ng226. Accessed August 2023.
28. Brophy RH, Fillingham YA. AAOS Clinical Practice Guideline Summary: Management of Osteoarthritis of the Knee (Nonarthroplasty), Third Edition. J Am Acad Orthop Surg. 2022 May 1;30(9):e721-e729. doi: 10.5435/JAAOS-D-21-01233.
29. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (NonArthroplasty) Evidence-Based Clinical Practice Guideline. https://www.aaos.org/oak3cpg Published August 30, 2021.
30. Palmetto GBA. Local Coverage Article: Billing and Coding: Hyaluronic Acid Injections for Knee Osteoarthritis (A59030). Centers for Medicare & Medicaid Services, Inc. Updated on 01/10/2023 with effective date 01/01/2023. Accessed September 2023.
31. National Government Services, Inc. Local Coverage Article: Billing and Coding: Hyaluronans Intra-articular Injections of (A52420). Centers for Medicare & Medicaid Services, Inc. Updated on 07/23/2021 with effective date 08/01/2021. Accessed September 2023.
32. Wisconsin Physicians Service Insurance Corporation. Local Coverage Article: Billing and Coding: Intraarticular Knee Injections of Hyaluronan (A56157). Centers for Medicare & Medicaid Services, Inc. Updated on 8/23/2022 with effective date 09/01/2022. Accessed September 2023.

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): J, M	**NCD/LCA/LCD Document (s):** A59030
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a59030&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

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): 5, 8	**NCD/LCA/LCD Document (s):** A56157

https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56157&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

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).