

## Hyaluronic Acid Derivatives:

Durolane<sup>®</sup>, Euflexxa<sup>™</sup>, Gel-One<sup>®</sup>, GelSyn-3<sup>™</sup>, GenVisc 850<sup>®</sup>, Hyalgan<sup>™</sup>, Hymovis<sup>®</sup>, Monovisc<sup>®</sup>, Orthovisc<sup>™</sup>, Supartz/Supartz FX<sup>™</sup>, Synjojoynt<sup>™</sup>, Synvisc<sup>™</sup>, & Synvisc-One<sup>™</sup>, TriVisc<sup>™</sup>, VISCO-3<sup>™</sup>, Triluron<sup>™</sup>, sodium hyaluronate 1% (Intra-articular)

Document Number: IC-0061

Last Review Date: 03/03/2020

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

### I. Length of Authorization

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

### II. 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
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
sodium hyaluronate 20 mg/2 mL injection	3	6	180
Supartz 25 mg/2.5 mL injection	5	10	180
Supartz FX 25 mg/2.5 mL injection	5	10	180
Synjojoynt 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 25 mg/2.5 mL injection	3	6	180

Triluron 20 mg/2 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)*
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
sodium hyaluronate	J3490	1 dose	1	3	6
Synjoynt	J7331	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 J7333**	1 dose	1	3	6
Triluron	J7332	1 mg	20	3	120

\*Max units are based on administration to both knees

\*\* Effective 07/01/2020

**III. Initial Approval Criteria**

- Gel-One and Euflexxa are the plan's preferred hyaluronic acid derivatives. Patients must have tried and have had an inadequate response, contraindication, or intolerance to BOTH of the preferred products prior to using a non-preferred product.

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**
- 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**
- 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)

† FDA Approved Indication(s)

#### IV. Renewal Criteria

- Gel-One and Euflexxa are the plan's preferred hyaluronic acid derivatives. Patients must have tried and have had an inadequate response, contraindication, or intolerance to BOTH of the preferred products prior to using a non-preferred product.

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
sodium hyaluronate	20 mg intra-articularly once weekly x 3 administrations
Supartz/Supartz FX	25 mg intra-articularly once weekly x 5 administrations

Synojoynt	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-articularly once weekly x 3 administrations
VISCO-3	25 mg intra-articularly once weekly x 3 administrations
Triluron	20 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
Euflexxa	J7323	1 dose	20 mg/2 mL	3	55566-4100-xx
Durolane	J7318	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
sodium hyaluronate	J3490	1 dose	20 mg/2 mL	3	57844-0181-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 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	1 mg	25 mg/2.5 mL	3	50563-0006-xx
VISCO-3	J7321 J7333*	1 dose	25mg/2.5 mL	3	87541-0301-xx
Triluron	J7332	1 mg	20 mg/2 mL	3	89122-0879-xx

\* Effective 07/01/2020

## VII. References

1. Sodium Hyaluronate 1% [package insert]. North Wales, PA; Teva Pharmaceuticals; March 2019. Accessed September 2019.

2. Supartz/Supartz FX [package insert]. Durham, NC; Bioventus LLC; April 2015. Accessed June 2019.
3. Hyalgan [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; May 2014. Accessed June 2019.
4. Euflexxa [package insert]. Parsippany, NJ; Ferring Pharmaceuticals; July 2016. Accessed June 2019.
5. Synvisc/Synvisc-One [package insert]. Ridgefield, NJ; Genzyme Biosurgery; September 2014. Accessed June 2019.
6. Orthovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; September 2014. Accessed June 2019.
7. Gel-One [package insert]. Warsaw, IN; Zimmer; May 2011. Accessed August 2018.
8. Monovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; February 2014. Accessed June 2019.
9. GelSyn-3 [package insert]. Durham, NC; Bioventus LLC; February 2016; Accessed June 2019.
10. GenVisc 850 [package insert]. Doylestown, PA; OrthogenRx, Inc; March 2016; Accessed June 2019.
11. Hymovis [package insert]. Florham Park, NJ; Fidia Pharma USA Inc.; October 2015. Accessed June 2019.
12. VISCO-3 [package insert]. Durham, NC; Bioventus LLC; December 2015. Accessed June 2019.
13. Durolane [package insert]. Durham, NC; Bioventus LLC; September 2017. Accessed June 2019.
14. Trivisc [package insert]. Doylestown, PA; OrthogenRx, Inc; November 2017. Accessed June 2019.
15. Synojoynt [package insert]. North Wales, PA; Teva Pharmaceuticals USA, Inc; June 2018. Accessed June 2019.
16. Triluron [package insert]. Florham Park, NJ; Fidia Pharma USA Inc.; March 2019. Accessed February 2020.
17. 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.
18. 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.
19. Brown GA. AAOS clinical practice guideline: treatment of osteoarthritis of the knee: evidence-based guideline, 2<sup>nd</sup> edition. *J Am Acad Orthop Surg*. 2013 Sep;21(9):577-9. doi: 10.5435/JAAOS-21-09-577.
20. 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.

21. 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.
22. 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.
23. 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.
24. Novitas Solutions, Inc. Local Coverage Determination (LCD): Hyaluronan Acid Therapies for Osteoarthritis of the Knee (DL35427). Centers for Medicare & Medicaid Services, Inc. Updated on (proposed draft) with effective date (proposed draft). Accessed June 2019.
25. Palmetto GBA. Local Coverage Determination (LCD): Hyaluronate Polymers (L33432). Centers for Medicare & Medicaid Services, Inc. Updated on 12/13/2018 with effective date 01/1/2019. Accessed June 2019.
26. First Coast Service Options, Inc. Local Coverage Determination (LCD): Viscosupplementation Therapy for Knee (L33767). Centers for Medicare & Medicaid Services, Inc. Updated on 02/01/2019 with effective date 01/08/2019. Accessed June 2019.
27. 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 12/19/2018 with effective date 1/1/2019. Accessed June 2019.
28. 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 3/29/2019 with effective date 5/20/2019. Accessed June 2019.

## 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):

<b>Jurisdiction(s):</b> L, H	<b>NCD/LCD Document (s):</b> L35427
<a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35427&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L35427&amp;bc=gAAAAAAAAAAAAAA==</a>	
<b>Jurisdiction(s):</b> J, M	<b>NCD/LCD Document (s):</b> L33432
<a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33432&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33432&amp;bc=gAAAAAAAAAAAAAA==</a>	
<b>Jurisdiction(s):</b> N	<b>NCD/LCD Document (s):</b> L33767
<a href="https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33767&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33767&amp;bc=gAAAAAAAAAAAAAA==</a>	
<b>Jurisdiction(s):</b> 6, K	<b>NCD/LCD Document (s):</b> A52420
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52420&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52420&amp;bc=gAAAAAAAAAAAAAA==</a>	
<b>Jurisdiction(s):</b> H, L	<b>NCD/LCD Document (s):</b> A55036
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A55036&amp;bc=gAAAAAAAAAAAAAA==">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A55036&amp;bc=gAAAAAAAAAAAAAA==</a>	

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

**Medicare Part B Administrative Contractor (MAC) Jurisdictions**

<b>Jurisdiction</b>	<b>Applicable State/US Territory</b>	<b>Contractor</b>
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