

**Hyaluronic Acid Derivatives (Euflexxa™, Hyalgan™, Gel-One®, Orthovisc™, Supartz/Supartz FX™, Synvisc™, Synvisc-One™, Monovisc®, Gel-Syn™, GenVisc 850®, Hymovis®)**

**\*IH\***

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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]: per knee**

- Euflexxa: Maximum 6 injections per 180 days
- Hyalgan: Maximum 10 injections per 180 days
- Gel-One: Maximum 2 injections per 180 days
- Gel-Syn: Maximum 6 injections per 180 days
- GenVisc 850: Maximum 5 injections per 180 days
- Monovisc: Maximum 2 injections per 180 days
- Orthovisc: Maximum 8 injections per 180 days
- Supartz/Supartz FX: Maximum 10 injections per 180 days
- Synvisc: Maximum 6 injections per 180 days
- Synvisc-One: Maximum 2 injections per 180 days
- Hymovis: Maximum 4 injections per 180 days

**B. Max Units (per dose and over time) [Medical Benefit]:**

**J7321 (Hyalgan & Supartz/Supartz FX) per knee**

**Male**                      5 units every 180 days

Female 5 units every 180 days

**J7323 (Euflexxa) per knee**

Male 3 units every 180 days

Female 3 units every 180 days

**J7324 (Orthovisc) per knee**

Male 4 units every 180 days

Female 4 units every 180 days

**J7325 (Synvisc/Synvisc-One) per knee**

Male 48 units every 180 days

Female 48 units every 180 days

**J7326 (Gel-One) per knee**

Male 1 unit every 180 days

Female 1 unit every 180 days

**J7327 (Monovisc) per knee**

Male 1 unit every 180 days

Female 1 unit every 180 days

**J7328 (Gel-Syn) per knee**

Male 504 units every 180 days

Female 504 units every 180 days

**Q9980 (GenVisc 850) per knee**

Male 125 units every 180 days

Female 125 units every 180 days

**J3490 (Hymovis) per knee**

Male 2 doses (24 mg/3 mL) every 180 days

Female 2 doses (24 mg/3 mL) every 180 days

### 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)

Client Specific Information
<ul style="list-style-type: none"> <li>• Patient has tried and failed to respond or tolerate Euflexxa in the same knee joint previously</li> </ul>

†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

#### V. Dosage/Administration (per knee)

Indication	Dose
Euflexxa	20 mg once weekly x 3 doses
Gel-One	30 mg x 1 dose
Gel-Syn	16.8 mg once weekly x 3 doses
GenVisc 850	25 mg once weekly x 5 doses
Hyalgan	20 mg once weekly x 5 doses
Monovisc	88 mg x 1 dose
Orthovisc	30 mg once weekly x 4 doses
Supartz/Supartz FX	25 mg once weekly x 5 doses
Synvisc	16 mg once weekly x 3 doses
Synvisc-One	48 mg x 1 dose

Hymovis	24 mg once weekly x 2 doses
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## VI. Billing Code/Availability Information

### Jcode:

- J7321 - Hyalgan (Fidia) 20 mg injection: 1 billing unit = 20 mg
- J7321 – Supartz/Supartz FX(Seikagaku) 25 mg injection: 1 billing unit = 25 mg
- J7323 – Euflexxa – (Ferring) 20 mg injection: 1 billing unit = 20 mg
- J7324 – Orthovisc – (Anika) 30 mg injection: 1 billing unit = 30 mg
- J7325 – Synvisc (Genzyme) 16 mg injection: 1 billing unit = 1 mg
- J7325 – Synvisc-One (Genzyme) 48 mg injection: 1 billing unit = 1 mg
- J7326 – Gel-One (Seikagaku) 30 mg injection: 1 billing unit = 30 mg
- J7327- Monovisc (Anika Therapeutics) 88 mg injection: 1 billing unit = 88 mg (1 dose)
- J7328 - Gel-Syn (IBSA) 16.8 mg injection: 1 billing unit = 0.1 mg
- Q9980 - GenVisc 850 (TEDEC) 25 mg injection: 1 billing unit = 1 mg
- J3490 – Unclassified drugs – Hymovis (Fidia) 24 mg/3 mL injection: 1 billing unit = 24 mg

### NDC:

- N/A

## VII. References

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9. Gel-Syn [package insert]. Lodi, Italy; IBSA; June 2015; Accessed February 2016.
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17. First Coast Service Options, Inc. Local Coverage Determination (LCD): Viscosupplementation Therapy For Knee (L33767). Centers for Medicare & Medicaid Services, Inc. Updated on 1/20/2016 with effective date 1/1/2016. Accessed February 2016.
18. 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 L25820 (A52420). Centers for Medicare & Medicaid Services, Inc. Updated on 12/24/2015 with effective date 1/1/2016. Accessed February 2016.

## Appendix 1 – Covered Diagnosis Codes

ICD-9 Codes	Diagnosis
715.16	Osteoarthrosis, localized, primary, lower leg
715.26	Osteoarthrosis, localized, secondary, lower leg
715.36	Osteoarthrosis, localized, not specified whether primary or secondary, lower leg
715.96	Osteoarthrosis, unspecified whether generalized or localized, lower leg

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> 5, 8	<b>NCD/LCD Document (s):</b> L34525
<a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34525&amp;ver=14&amp;Date=02%2f10%2f2016&amp;DocID=L34525&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34525&amp;ver=14&amp;Date=02%2f10%2f2016&amp;DocID=L34525&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAA%3d%3d&amp;</a>	

<b>Jurisdiction(s):</b> 12 (L), H	<b>NCD/LCD Document (s):</b> L35427
<a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35427&amp;ver=16&amp;Date=02%2f10%2f2016&amp;DocID=L35427&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35427&amp;ver=16&amp;Date=02%2f10%2f2016&amp;DocID=L35427&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAA%3d%3d&amp;</a>	

<b>Jurisdiction(s):</b> 11(M)	<b>NCD/LCD Document (s):</b> L33432
<a href="https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33432&amp;ver=11&amp;Date=02%2f10%2f2016&amp;DocID=L33432&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33432&amp;ver=11&amp;Date=02%2f10%2f2016&amp;DocID=L33432&amp;SearchType=Advanced&amp;bc=KAAAAAgAAAAAA%3d%3d&amp;</a>	

<b>Jurisdiction(s):</b> 9(N)	<b>NCD/LCD Document (s):</b> L33767
<a href="https://www.cms.gov/medicare-coverage-database/details/lcd-">https://www.cms.gov/medicare-coverage-database/details/lcd-</a>	

<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?LCDId=33767&ver=10&Date=02%2f10%2f2016&DocID=L33767&SearchType=Advanced&bc=KAAAAAgAAAAAAA%3d%3d&>

Jurisdiction(s): 6, K

NCD/LCD Document (s): A52420

<https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52420&ver=11&Date=02%2f10%2f2016&DocID=A52420&SearchType=Advanced&bc=JAAAAAgAAAAAAA%3d%3d&>

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

Jurisdiction	Applicable State/US Territory	Contractor
E	CA, HI, NV, AS, GU, CNMI	Noridian Administrative Services (NAS)
F	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Administrative Services (NAS)
5	KS, NE, IA, MO	Wisconsin Physicians Service (WPS)
6	MN, WI, IL	National Government Services (NGS)
H	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions
8	MI, IN	Wisconsin Physicians Service (WPS)
9 (N)	FL, PR, VI	First Coast Service Options
10 (J)	TN, GA, AL	Cahaba Government Benefit Administrators
11 (M)	NC, SC, VA, WV	Palmetto GBA
12 (L)	DE, MD, PA, NJ, DC	Novitas Solutions
K	NY, CT, MA, RI, VT, ME, NH	National Government Services (NGS)
15	KY, OH	CGS Administrators, LLC