

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[™], & sodium hyaluronate 1% (Intra-articular)

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I. Length of Authorization

Coverage will be provided for 6 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 |
|---|---------------------|-----------------------|-------------|
| 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 |
| 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 |
| Synojoynt 20 mg/2 mL | 3 | 6 | 180 |

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|----------------------------------|---|---|-----|
| 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 |
| sodium hyaluronate | J7331 | 1 mg | 20 | 3 | 120 |
| Synjoynt | 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:

- Patient must try and have an inadequate response, contraindication, or intolerance to Euflexxa

Universal Criteria ^{1-16,24-26}

- 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 †

- Patient has a radiographically* confirmed diagnosis of osteoarthritis of the knee; **AND**
- Trial and failure of conservative therapy (including physical therapy AND 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)

**Note: Imaging is not required to make the diagnosis in patients with a typical presentation of OA²⁷*

† FDA Approved Indication(s)

IV. Renewal Criteria ^{1-16,24-26}

Coverage can be renewed based upon the following criteria:

- | |
|--|
| <ul style="list-style-type: none"> • Patient must try and have an inadequate response, contraindication, or intolerance to Euflexxa |
|--|
- 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 the following: 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 |
| sodium hyaluronate | 20 mg intra-articularly once weekly x 3 administrations |
| Synojynt | 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 |
| sodium hyaluronate | J7331 | 1 mg | 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 |
| Synojynt | 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

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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 | |
| 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 |