

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[™], Triluron[™], sodium hyaluronate 1% (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) [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 |
| Synjoynt 20 mg/2 mL injection | 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 |
| 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 |
| Synojynt | 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

- DMBA ONLY covers Synvisc, Synvisc-ONE and Euflexxa. All other Hyaluronic Acid Derivatives will NOT be covered.

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

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| <ul style="list-style-type: none"> ▪ DMBA ONLY covers Synvisc, Synvisc-ONE and Euflexxa. All other Hyaluronic Acid Derivatives will NOT be covered. |
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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 |

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|--------------------|---|
| 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 |
| 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-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 |
| Synjoynt | 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 |

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 |

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|--------|--|
| 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): 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 |

Medicare Part B Administrative Contractor (MAC) Jurisdictions

| Jurisdiction | Applicable State/US Territory | Contractor |
|--------------|---|---|
| 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 |