Blue Cross Blue Shield Blue Care Network of Michigan

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Effective Date: 10/03/2024

Hyaluronic Acid Intra-Articular Injections

Brand	HCPCS	Benefit
Durolane	J7318	Medical
Euflexxa	J7323	Medical
Gel-One	J7326	Medical
Gelsyn-3	J7328	Medical
GenVisc 850	J7320	Medical
Hyalgan	J7321	Medical
Hymovis	J7322	Medical
Monovisc	J7327	Medical
Orthovisc	J7324	Medical
Supartz, FX	J7321	Medical
Synojoynt	J7331	Medical
Synvisc	J7325	Medical
Synvisc–One	J7325	Medical
Triluron	J7332	Medical
TriVisc	J7329	Medical
Visco-3	J7321	Medical

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria:
   a. Commercial Benefit
      i. Please refer to the BCBSM/BCN utilization management medical drug list for covered hyaluronic acid products.
   b. Medicare Benefit
      i. Treatment of osteoarthritis of the knee
      ii. Trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
    a. Quantity Limits: Align with FDA recommended dosing
    b. Authorization Period: FDA recommended duration of treatment
    c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Osteoarthritis (OA) is a common degenerative condition affecting the knees. It is characterized by deterioration and loss of the articular cartilage, subchondral sclerosis and osteophyte formation, and is often accompanied by inflammation of the synovium. Currently, no curative therapy is available for osteoarthritis and thus the overall goals of management are to reduce pain and prevent disability.

- Hyaluronan, also known as hyaluronate, hyaluronic acid or viscosupplementation, is a naturally occurring macromolecule that is a major component of synovial fluid and is thought to contribute to its viscoelastic properties. To date, over ten hyaluronans have received FDA approval, each using the 515 device approval path, which is obtained simply by demonstrating that the product is similar to a previously approved device. Current literature and guideline recommendations do not support the use of one hyaluronic acid product over another.

- FDA approved hyaluronic acid agents are indicated for the treatment of pain in knee OA in patients 18 years of age and older who have failed nonpharmacologic treatment and simple analgesics or NSAIDs. Knee OA requires a comprehensive plan for management, including physical, psychological, and/or pharmacologic therapies. The approved use for hyaluronic acid products aligns with the treatment recommendations laid out in the most recent guidelines for management of knee OA.

- 2019 American College of Rheumatology (ACR)/Arthritis Foundation (AF) Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee:

    - The 2019 ACR/AF guidelines strongly recommend the use of exercise, self-management programs, weight loss, tai chi, and gait aids (i.e. tibiofemoral knee brace, cane) in nonpharmacologic management of knee OA. Heat and therapeutic cooling, cognitive behavioral therapy, kinesiotaping, and yoga are additional nonpharmacologic options conditionally recommended for managing knee OA.

    - With regard to pharmacologic approaches to treatment, the guidelines strongly recommend the use of topical NSAIDs, keeping with the principle that local therapies with minimal systemic exposure are preferable prior to systemic. Oral NSAIDs and intra-articular glucocorticoids are also strongly recommended, with NSAIDs being the initial oral treatment of choice for knee OA. Acetaminophen, duloxetine, and tramadol are conditionally recommended.

    - Intraarticular hyaluronic acid injections are conditionally recommended against in patients with knee OA due to a lack of data demonstrating consistent benefit without trial bias; however, in clinical practice the choice to use hyaluronic acid in patients with knee OA who have had an inadequate response to nonpharmacologic and pharmacologic therapies may be more favorable than offering no intervention.

- 2019 Osteoarthritis Research Society International (OARSI) Guidelines for the Non-surgical Management of Knee, Hip, and Polyarticular Osteoarthritis.

- The 2019 OARSI guidelines strongly emphasize core treatments (i.e. arthritis education, land-based exercise programs, mind-body exercise, dietary management) for all patients prior to initiating therapy.

- Pharmacologic and nonpharmacologic treatments with a high consensus recommendation include aquatic exercise, gait aids, topical NSAIDs, oral NSAIDs, and intraarticular corticosteroids. Treatment with intra-articular hyaluronic acid is a low consensus recommendation and is conditionally recommended after achieving an inadequate response to high consensus treatment options.

- The use of acetaminophen for knee OA was conditionally not recommended, while the use of oral and transdermal opioids was strongly not recommended.

- The 2021 American Academy of Orthopaedic Surgeons (AAOS) Evidence-Based Clinical Practice Guideline for the Management of OA of the Knee (Non-Arthroplasty) does not recommend hyaluronic acid intraarticular injection(s) for routine use in the treatment of symptomatic OA of the knee (moderate strength recommendation). Though clinical trial results evaluating benefit with HA treatment have been mixed, the gudelines acknowledge that some studies have demonstrated statistically significant improvement in OA symptoms with the use of HA. As such, the group agrees that viscosupplementation may represent a viable option for select patient groups, particularly those that failed other treatments when appropriately indicated.

- Of note, the above guideline recommendations apply to patients with knee OA and no contraindications to recommended therapies. The choice of treatment(s) should be individualized to the patient, evaluating for contraindications, comorbidities, disease severity, past medical/surgical history, and personal preferences.

References:

1. Bannuru RR, Osani, MC, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis.Osteoarth Cart 2019: 27: 1578-1589.
2. Rutjes AWS, Juni P, da Costa BR, et al. Viscosupplementation for osteoarthritis of the knee. Ann Int Med 2012;
3. WPS. Local Coverage Determination: Intra-articular Injections of Hyaluronan (L30149). Rev: 6/1/14, revision 4.
4. Kolasinski, SL, Neogi T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Mangement of Osteoarthritis of the Hand, Hip, and Knee. Arth Care & Res 2020; 72: 149-162.
5. Supartz FX [package insert]. Durham, NC; Bioventus LLC; April 2015.
6. Hyalgan [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; May 2014.
7. Euflexxa [package insert]. Parsippany, NJ; Ferring Pharmaceuticals; July 2016.
8. Synvisc/Synvisc-One [package insert]. Ridgefield, NJ; Genzyme Biosurgery; September 2014.
9. Orthovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; September 2014.
10. Gel-One [package insert]. Warsaw, IN; Zimmer; May 2011.
11. Monovisc [package insert]. Raynham, MA; DePuy Mitek, Inc.; February 2014.
12. GelSyn-3 [package insert]. Durham, NC; Bioventus LLC; February 2016;
13. GenVisc 850 [package insert]. Doylestown, PA; OrthogenRx, Inc; September 2015.
14. Hymovis [package insert]. Parsippany, NJ; Fidia Pharma USA Inc.; October 2015.
15. Durolane [package insert]. Durham, NC; Bioventus LLC; September 2017.
16. Trivisc [package insert]. Doylestown, PA; OrthogenRx, Inc; November 2017.
17. Synjoynt [package insert]. North Wales, PA; Teva Pharmaceuticals, Inc.
18. Triluron [package insert]. Florham Park, NJ; Fidia Pharma USA, Inc.; July 2019.
19. American Academy of Orthopaedic Surgeons Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline. https://www.aaos.org/oak3cpg Published August 30, 2021. Accessed August 22, 2023.

Policy History		
#	Date	Change Description
1.9	Effective Date: 10/03/2024	Annual review of criteria was performed, no changes were made
1.8	Effective Date: 10/12/2023	Annual review of criteria was performed, no changes were made
1.7	Effective Date: 10/06/2022	Annual review of criteria was performed, no changes were made
1.6	Effective Date: 10/07/2021	Removed Medicare criteria requiring trial and failure of pharmacologic and non-pharmacologic therapy, and FDA approved age
1.5	Effective Date: 10/08/2020	Changed age requirement, quantity limits, authorization period, and renewal criteria to reflect standard verbiage Updated coverage criteria as follows: - Added topical NSAIDs and duloxetine to list of pharmacologic agents in bullet i. - Removed topical and oral NSAID requirement as it conflicted with bullet i. - Removed bullet stating contraindications to NSAIDs qualifies for coverage; other guideline-approved treatment options are listed and available
1.4	Effective Date: 01/01/2019	PA added to Gel-one, GelVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Synvisc, Synvisc-One, TriVisc, Visco-3, Synojoynt, and Triluron for MAPPO and BCNA
1.3	Effective Date: 11/07/2019	Updated criteria to remove exclusion from commercial medical benefit
1.2	Effective Date: 02/14/2019	Policy updated to include Trivisc and Durolane
1.1	Effective Date: 02/08/2018	Updated to exclude all HA products from the medical benefit
1.0	Effective Date: 10/20/2019	Policy and Criteria Update

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*