Department:	Pharmacy Management	**Original Approval:**	07/24/2017
Policy #:	PM144	**Last Approval:**	09/12/2019
Title:	Hyaluronic acid derivatives (such as Durolane®, Euflexxa®, Gel-One®, Gelsyn-3™, GenVisc® 850, Hyalgan®, Hymovis®, Monovisc®, Orthovisc®, Supartz®/Supartz FX™, Synojoynt™ , Synvisc®, Synvisc-One®,TriVisc™,Visco-3™)		
Approved By:	UM Pharmacy Subcommittee		

The purpose of this policy is to clarify and/or supplement the WA HCA Health Technology Assessment (HTA) or CMS Local Coverage Determination (LCD) Guidelines.

REQUIRED CLINICAL DOCUMENTATION FOR REVIEW

Documentation required to determine medical necessity for Hyaluronic acid derivatives (Euflexxa, Gel-One, Gelsyn-3, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz/Supartz FX, Synojoynt, Synvisc, Synvisc-One): History and/or physical examination notes and relevant specialty consultation notes that address the problem and need for the service: -Diagnosis -Medication list (current and past) -Current and past treatment modalities, including physical therapy -Product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physiatrist -Dosing and duration of therapy -Imaging/Radiology.

BACKGROUND

Hyaluronic acid derivatives (HADs) are indicated for the treatment of pain related to knee osteoarthritis (OA) in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics (e.g., acetaminophen).[1-10] The use of intra-articular (IA) injections of HADs are to restore the normal properties (viscosity and elasticity) of the synovial fluid. Other effects of these products have been noted, which include free radical scavenging and antinociceptive effects.[11] Gel-One, Hyalgan, Supartz/FX, Synvisc/Synvisc-One, and Visco-3 are derived from rooster or chicken combs. The remaining products are derived from non-avian sources and may be useful for patients with allergies to eggs or poultry products. Non-avian-sourced products may be preferred in patients with allergies to avian proteins and products (e.g., eggs, feathers). GenVisc 850 has data to support similarity to Supartz/Supartz FX.[9] Visco-3 is equivalent to three injections of Supartz/Supartz FX and TriVisc is equivalent to GenVisc 850. Although retreatment data are limited, all of the HAD products have data concerning efficacy and/or safety of repeat courses.[1-10,15] In many cases, at least 6 months was required or a minimum of 6 months had elapsed prior to injection of a repeat course.[3,5-6,9,16-17]

Product	Directions for Use, Intra-articular	How Supplied (dose is per knee)
Durolane	60 mg (3 mL) once	In 3 mL prefilled syringes.

		sodium hyaluronate 20 mg/mL
Euflexxa	3 injections given one week apart.	Single-use 2.25 mL glass syringe. 20 mg sodium hyaluronate/2 mL.
Gel-One	1 injection	Single-use 3 mL prefilled syringe. 30 mg cross-linked hyaluronate/3 mL.
Gelsyn-3	IA injection (2 mL) QW for 3 weeks.	Single-use 2 mL prefilled syringe. 16.8 mg sodium hyaluronate/2 mL.
GenVisc 850	5 injections given one week apart. Some patients may benefit from 3 injections.	Single-use 3 mL prefilled syringe. 25 mg sodium hyaluronate/2.5 mL.
Hyalgan	5 injections given one week apart. Some patients may benefit from 3 injections.	Single-use 2 mL vials and prefilled syringes. 20 mg sodium hyaluronate/2 mL.
Hymovis	1 injection weekly for 2 weeks	Single-use 3 mL injection in a 5-mL syringe 8 mg hyaluronan per 1 mL (24 mg/3 mL)
Monovisc	1 injection	Single-use 5 mL syringe. 88 mg hyaluronan/4 mL.
Orthovisc	3 or 4 injections given one week apart.	Single-use 3 mL syringe. 30 mg hyaluronan/2 mL.
Synvisc	3 injections given one week apart.	Single-use 2.25 mL glass syringe. 16 mg hylan polymers/2 mL.
Synojoynt	3 injections given one week apart.	Single use prefilled syringe with 2ml injection. 1% Sodium hyaluronate
Synvisc-One	1 injection.	Single-use 10 mL glass syringe. 48 mg hylan polymers/6 mL.
Hyalgan	5 injections given one week apart. Some patients may benefit from 3 injections.	Single-use 2 mL vials and prefilled syringes. 20 mg sodium hyaluronate/2 mL.
Supartz/Supartz FX	5 injections given one week apart. Some patients may benefit from 3 injections.	Single-use 2.5 mL prefilled syringe. 25 mg sodium hyaluronate/2.5 mL.
Trivisc	3 injections given one week apart	In 3ml prefilled syringe 25mg sodium hyaluronate/3ml
Visco-3	25 mg (2.5 mL) once weekly for 3 weeks	In 2.5 mL prefilled syringes sodium hyaluronate 10 mg/mL

Guidelines

Guidelines for the medical management of OA of the hand, hip, and knee were published in 2012 by the American College of Rheumatology (ACR).[12] Initial pharmacologic therapy for knee OA consists of acetaminophen, oral and topical non-steroidal anti-inflammatory drugs (NSAIDs), tramadol, and IA corticosteroid injections. IA HA, duloxetine, and opioids are recommended in certain conditions, including patients who failed to respond to initial therapies for *knee* OA. IA HA is not recommended in

patients with hand or hip OA. In the guidelines, no distinction is made between the available IA HA products or between products with various molecular weights.

The American Academy of Orthopaedic Surgeons (AAOS) updated guidelines (2013) for the treatment of OA of the knee (non-arthroplasty) mention HA derivatives.[13] However, the guidelines note that HA cannot be recommended for patients with symptomatic OA of the knee. This recommendation is based on an analysis that included 14 studies demonstrating that the effect of HA injections was unlikely to provide a clinically important benefit based on the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and visual analog scale (VAS) pain and WOMAC function on the basis of age, baseline pain scores, body mass index (BMI), weight, and gender. AAOS noted that when the high- and low-molecular weight products were analyzed, most of the statistically significant outcomes were associated with the high-molecular cross-linked HA, but when compared to mid-range molecular weight products, statistical significance was not maintained. The guidelines specifically note that treatment comparisons between any weights higher than 750 kDa were not significantly different. It is also noted that other reviews (e.g., by the Agency for Healthcare Research and Quality [AHRQ]) demonstrate a statistically significant treatment effect using different selection criteria. AAOS acknowledges that lower-strength studies were excluded from the AAOS review based on selection criteria, and states that other agencies have acknowledged that there is evidence of potential publication bias with HA products.

The OA Research Society International (OARSI) also has guidelines for knee OA (2014).[14]
[14] These guidelines note that use of IA HA is uncertain in knee OA and not appropriate for multiple-joint OA. It was noted that inconsistent conclusions among meta-analyses and conflicting results regarding safety influenced the recommendation.
DEFINITIONS
None

INDICATIONS/CRITERIA

Medicaid Members	***See WA HCA HTA 20131114A – Hyaluronic Acid/ Viscosupplementation: https://www.hca.wa.gov/about-hca/health-technology-assessment/hyaluronic-acidviscosupplementation***
Medicare Members	***Local Coverage Determination (LCD): Intra-articular Injections of Hyaluronan (L34525)* has been retired. Follow the criteria below.** ***Step-utilization of Part D drugs not required.***

Coverage of hyaluronic acid derivatives is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Osteoarthritis (OA) of the Knee**.

Criteria. *Patient must meet the following criteria (A, B, AND C)*:

A) Initial Therapy. Approve an initial course if the patient meets ALL of the following conditions (i, ii, and iii):

i. Diagnosis of the knee to be treated is confirmed by radiologic evidence of knee OA (e.g., x-ray, magnetic resonance imaging [MRI], computed tomography [CT] scan, ultrasound); AND

ii. The patient has tried at least TWO of the following three modalities of therapy for OA (i, ii, iii):

a) At least one course of physical therapy (PT) for knee osteoarthritis; OR

b) At least TWO of the following pharmacologic therapies [(1), (2), (3), (4)] **[verification of therapies required]**:

1. Nonsteroidal anti-inflammatory drug (NSAID), oral or topical (examples of oral agents include naproxen, ibuprofen, Celebrex® [celecoxib capsules]; examples of topical NSAIDs include: diclofenac solution [e.g., Pennsaid®] or diclofenac 1% gel [e.g., Voltaren® gel]) [NOTE: a trial of two or more NSAIDs {oral and/or topical} counts as one pharmacologic therapy];
2. Acetaminophen;
3. Tramadol (Ultram®/XR, generics);
4. Duloxetine (Cymbalta®, generics);

c) At least TWO injections of IA corticosteroids to the affected knee; AND

iii. The product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physical medicine and rehabilitation (physiatrist).

B) Patient has Already Received a Course of HAD in the Same Knee. Approve ONE repeat course if the patient meets ALL of the following conditions (i, ii, and iii):

i. At least 6 months have elapsed since the last injection with any hyaluronic acid derivative (HAD); AND

ii. The patient had a response to the previous course of hyaluronic acid derivative (HAD) therapy for osteoarthritis of the knee (e.g., reduced joint pain, tenderness, or morning stiffness, improved mobility) according to the prescribing physician and now requires additional therapy for osteoarthritis symptoms; AND

iii. The product is administered by or under the supervision of a physician specializing in rheumatology, orthopedic surgery, or physical medicine and rehabilitation (physiatrist).

These preparations are indicated for the treatment of pain related to knee OA for patients who have failed to adequately respond to other therapies (i.e., nonpharmacologic therapy, analgesics).[1-10] Many other pharmacologic therapies are approved and available for the treatment of knee OA. In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirements for confirmation of diagnosis by radiologic evidence.

Dosing in Osteoarthritis of the Knee. *Dosing must meet the following for the requested product*:[1-10]

Product	Number of injections per course
Durolane	One injection given one time
Euflexxa	Three injections given 1 week apart
Gel-One	One injection given one time
Gelsyn-3	Three injections given 1 week apart
GenVisc 850	Five injections given 1 week apart
Hyalgan	Five injections given 1 week apart
Hymovis	Two injections given 1 week apart

Monovisc	One injection given one time
Orthovisc	Three or four injections given 1 week apart
Synvisc	Three injections given 1 week apart
Synvisc-One	One injection given one time
Supartz/Supartz FX	Five injections given 1 week apart
TriVisc	Three injections given 1 week apart
Visco-3	Three injections given 1 week apart

* Dose is for one knee. If two knees are being treated, then each knee requires a syringe or vial of product.

Initial Approval.[1-10]

Product	Number of injections (doses) per course per knee
Durolane	One injection
Euflexxa	Three injections
Gel-One	One injection
Gelsyn-3	Three injections
GenVisc 850	Five injections (some will only use three)
Hyalgan	Five injections (some will only use three)
Hymovis	Two injections
Monovisc	One injection
Orthovisc	Three or four injections
Synvisc	Three injections
Synvisc-One	One injection
Supartz/Supartz FX	Five injections (some will only use 3)
TriVisc	Three injections
Visco-3	Three injections

Although retreatment data are limited, all of the HAD products have data concerning efficacy and/or safety of repeat courses.[1-10,15] In many cases, at least 6 months was required or a minimum of 6 months had elapsed prior to injection of a repeat course.[3,5-6,9,16-17] In the professional opinion of specialist physicians reviewing the data, we have adopted the criteria requirement for repeat courses.

Duration of Therapy. Duration of therapy varies depending on product. The course may be repeated if the patient had a response to the previous course.

Labs/Diagnostics. For initial approval, radiologic evidence of osteoarthritis of the affected knee is required as noted in the criteria section.

Waste Management.

The number of injections depends on which product is used. The entire vial or syringe is injected. If both knees are being treated then two syringes/vials will be needed.

Conditions Not Recommended for Approval

Hyaluronic acid derivatives have not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage of these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Acute Ankle Sprain.** A randomized, controlled, prospective trial was conducted which assessed the use of IA HA in acute ankle sprains.[18-19] Patients treated with IA HA (n = 79) within 48 hours of injury and again on Day 4 reported a time to pain-free and disability-free return to sport of 11 days (± 8 days) compared with 17 days (± 8 days) for placebo ($P < 0.05$).[18] All patients were also treated with standard of care (rest, ice, compression, and elevation [RICE]). At 24 months, the placebo group experienced an increase in repeat sprains when compared with those treated with HA (21 recurrent ankle sprains in the placebo group compared with 7 recurrent ankle sprains in the HA treatment group [$P < 0.001$]) as well as a significant difference in missed days from participation in sport activity (49 days vs. 12 days for the placebo and HA groups, respectively; $P < 0.001$).[19] More data are needed to determine the role of IA HA products in the treatment of acute ankle sprains.

2. **Osteoarthritis (OA) and Other Pathologic Conditions Involving Joints Other than the Knee** (e.g., hand, hip, ankle, shoulder OA, temporomandibular joint [TMJ], adhesive capsulitis of the shoulder, subacromial impingement). The prescribing information for these agents state in the precautions section that the safety and effectiveness of hyaluronic acid derivatives injections into joints other than the knee have not been established.[1-10] Due to the absence of evidence to support use of IA HA and potential for harm, the guidelines for the management of hand, hip, and knee OA by ACR (2012) do not recommend use of IA HA in patients with hand or hip OA.12 AAOS has published guidelines that mention HA as an option for glenohumoral (shoulder) joint OA.20 The guidelines note that the strength of evidence for using HA to treat this joint is weak even though each outcome in the single study evaluated did result in statistically significant improvement in pain relief, range of motion, and quality of life for patients with shoulder pain. Small trials have also investigated IA HA in other joints, including ankle OA21-28 and hip OA.[29-36] More data are needed to determine if there is a role for IA HA for the treatment of OA involving other joints. A small trial (n = 70) found that IA HA did not result in increased benefit for adhesive capsulitis of the shoulder (also known as frozen shoulder) in patients who were already receiving PT.37 Another small study (n = 159) did not show benefit of IA HA over corticosteroid or placebo injections in patients with subacromial impingement.[38]

3. **Pathologic Conditions of the Knee Other than Osteoarthritis (OA)** [e.g., chondromalacia patellae, osteochondritis dissecans, patellofemoral syndrome, post-anterior cruciate ligament {ACL} reconstruction]. HA products are indicated in knee OA.[1-10] Adequate, well-designed trials have not clearly established the use of IA HA in other conditions of the knee.[39-40]

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

References

1. Hyalgan® injection [prescribing information]. Parsippany, NJ: Fidia Pharma USA Inc; May 2014.
2. Synvisc® injection [prescribing information]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
3. Synvisc-One® injection [prescribing information]. Ridgefield, NJ: Genzyme Biosurgery; September 2014.
4. Supartz® FX™ [prescribing information]. Memphis, TN: Smith & Nephew; April 28, 2015.
5. Orthovisc® injection [prescribing information]. Raynham, MA: DePuy Mitek; not dated. Accessed on January 31, 2018. Available at: http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Brochures/Orthovisc%20Physician%20Brochure%20Final%209-14.pdf.
6. Euflexxa® injection [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals, Inc.; July 2016.
7. Gel-One® injection [prescribing information] Warsaw, IN: Zimmer (manufactured by Seikagaku Corporation, Tokyo, Japan); May 20, 2011.
8. Monovisc® [prescribing information]. Raynham, MA: DePuy Mitek, Inc./Johnson & Johnson; not dated. Accessed on January 31, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090031c.pdf. .
9. GenVisc® 850 [prescribing information]. Doylestown, PA: OrthogenRx; not dated. Accessed on January 31, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140005d.pdf.
10. Hymovis® [prescribing information]. Parsippany, NJ: Fidia Pharma USA; October 2015.

11. Adams ME, Lussier AJ, Peyron JG. A risk-benefit assessment of injections of hyaluronan and its derivatives in the treatment of osteoarthritis of the knee. *Drug Safety*. 2000;23(2):115-130.
12. 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.* 2012;64:465-474.
13. Jevsevar D, Brown GA, Jones DL, et al. Treatment of osteoarthritis of the knee, 2nd edition: summary of recommendations. May 18, 2013. Available at: http://www.aaos.org/research/guidelines/guidelineoaknee.asp. Accessed on October 6, 2018.
14. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. 2014;22(3):363-388.
15. Waddell DD, Joseph B. Delayed total knee replacement with Hylan G-F 20. *J Knee Surg*. 2016;29(2):159-168.
16. Navarro-Sarabia F, Coronel P, Collantes E, et al. A 40-month multicentre, randomised placebo-controlled study to assess the efficacy and carry-over effect of repeated intra-articular injections of hyaluronic acid in knee osteoarthritis: the AMELIA project. *Ann Rheum Dis*. 2011;70(11):1957-1962.
17. Raynauld JP, Goldsmith CH, Bellamy N, et al. Effectiveness and safety of repeat courses of hylan G-F 20 in patients with knee osteoarthritis. *Osteoarthritis Cartilage*. 2005;13(2):111-119.
18. Petrella RJ, Petrella MJ, Cogliano A. Periarticular hyaluronic acid in acute ankle sprain. *Clin J Sport Med*. 2007;17(4):251-257.
19. Petrella MJ, Cogliano A, Petrella RJ. Original research: long-term efficacy and safety of periarticular hyaluronic acid in acute ankle sprain. *Phys Sportsmed*. 2009;37(1):64-70.
20. Izquierdo R, Voloshin I, Edwards S, et al. Treatment of glenohumeral osteoarthritis. *J Am Acad Orthop Surg*. 2010;18(6):375-382.
21. Sun SF, Chou YJ, Hsu CW, et al. Efficacy of intra-articular hyaluronic acid in patients with osteoarthritis of the ankle: a prospective study. *Osteoarthritis Cartilage*. 2006;14(9):867-874.
22. Salk RS, Chang TJ, D'Costa WF, et al. Sodium hyaluronate in the treatment of osteoarthritis of the ankle: a controlled, randomized, double-blind, pilot study. *J Bone Joint Surg Am*. 2006;88(2):295-302.
23. Karatosun V, Unver B, Ozden A, et al. Intra-articular hyaluronic acid compared to exercise therapy in osteoarthritis of the ankle. A prospective randomized trial with long-term follow-up. *Clin Exp Rheumatol*. 2008;26(2):288-294.
24. Sun SF, Chou YJ, Hsu CW, Chen WL. Hyaluronic acid as a treatment for ankle osteoarthritis. *Curr Rev Musculoskelet Med*. 2009;2(2):78-82.
25. Cohen MM, Altman RD, Hollstrom R, et al. Safety and efficacy of intra-articular sodium hyaluronate (Hyalgan) in a randomized, double-blind study for osteoarthritis of the ankle. *Foot Ankle Int*. 2008;29(7):657-663.
26. Abate M, Pulcini D, Di Iorio A, Schiavone C. Viscosupplementation with intra-articular hyaluronic acid for treatment of osteoarthritis in the elderly. *Curr Pharm Des*. 2010;16(6):631-640.
27. DeGroot H 3rd, Uzunishvili S, Weir R, et al. Intra-articular injection of hyaluronic acid is not superior to saline solution injection for ankle arthritis: a randomized, double-blind, placebo-controlled study. *J Bone Joint Surg Am*. 2012;94(1):2-8.
28. Sun SF, Hsu CW, Sun HP, et al. The effect of three weekly intra-articular injections of hyaluronate on pain, function, and balance in patients with unilateral ankle arthritis. *J Bone Joint Surg Am*. 2011;93(18):1720-1726.
29. Tikiz C, Unlu Z, Sener A, et al. Comparison of the efficacy of lower and higher molecular weight viscosupplementation in the treatment of hip osteoarthritis. *Clin Rheumatol*. 2005;24:244-250.

30. Migliore A, Tormenta S, Severino L, et al. The symptomatic effects of intra-articular administration of hylan G-F 20 on osteoarthritis of the hip: clinical data of 6 months follow-up. *Clin Rheumatol*. 2006;25(3):389-393.
31. Qvistgaard E, Christensen R, Torp-Pedersen S, Bliddal H. Intra-articular treatment of hip osteoarthritis: a randomized trial of hyaluronic acid, corticosteroid, and isotonic saline. *Osteoarthritis Cartilage*. 2006;14(2):163-170.
32. Caglar-Yagci H, Unsal S, Yagci I, et al. Safety and efficacy of ultra-sound guided intra-articular hylan G-F 20 injection in osteoarthritis of the hip: a pilot study. *Rheumatol Int*. 2005;25(5):341-344.
33. Conrozier T, Vignon E. Is there evidence to support the inclusion of viscosupplementation in the treatment paradigm for patients with hip osteoarthritis? *Clin Exp Rheumatol*. 2005;23(5):711-716.
34. Van Den Bekerom MPJ. Viscosupplementation in symptomatic severe hip osteoarthritis: a review of the literature and report on 60 patients. *Acta Orthop Belg*. 2006;72:560-568.
35. Fernandez Lopez JC, Ruano-Ravina A. Efficacy and safety of intraarticular hyaluronic acid in the treatment of hip osteoarthritis: a systematic review. *Osteoarthritis Cartilage*. 2006;14(12):1306-1311.
36. Richette P, Ravaud P, Conrozier T, et al. Effect of hyaluronic acid in symptomatic hip osteoarthritis: a multicenter, randomized, placebo-controlled trial. *Arthritis Rheum*. 2009;60(3):824-830.
37. Hsieh LF, Hsu WC, Lin YJ, et al. Addition of intra-articular hyaluronate injection to physical therapy program produces no extra benefits in patients with adhesive capsulitis of the shoulder: a randomized controlled trial. *Arch Phys Med Rehabil*. 2012;93(6):957-964.
38. Penning LI, de Bie RA, Walenkamp GH. The effectiveness of injections of hyaluronic acid or corticosteroid in patients with subacromial impingement: a three-arm randomised controlled trial. *J Bone Joint Surg Br*. 2012;94(9):1246-1252.
39. Tang X, Pei FX, Zhou ZK, et al. A randomized, single-blind comparison of the efficacy and tolerability of hyaluronate acid and meloxicam in adult patients with Kashin-Beck disease of the knee. *Clin Rheumatol*. 2012;31(7):1079-1086.
40. Chau JY, Chan WL, Woo SB, et al. Hyaluronic acid instillation following arthroscopic anterior cruciate ligament reconstruction: a double-blinded, randomised controlled study. *J Orthop Surg (Hong Kong)*. 2012;20(2):162-165.
41. Gelsyn-3 [prescribing information]. Pambio-Noranco, Switzerland: IBSA; 2016.
42. Visco-3 [prescribing information]. Durhan, NC: Bioventus; not dated. Accessed on January 31, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf/p980044s027d.pdf.
43. Durolane [prescribing information]. Durham, NC: Bioventus; not dated. Accessed on January 31, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170007D.pdf.
44. Trivisc [prescribing information]. Doylestown, PA: OrthogenRx; not dated. Accessed on January 31, 2018. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160057D.pdf.
45. Synojoint [prescribing information]. North Wales, PA: Teva; not dated.

Other References Utilized

- Strand V, Baraf HS, Lavin PT, et al. A multicenter, randomized controlled trial comparing a single intra-articular injection of Gel-200, a new cross-linked formulation of hyaluronic acid, to phosphate buffered saline for treatment of osteoarthritis of the knee. *Osteoarthritis Cartilage*. 2012;20(5):350-356.

CFR	42 CFR § 438.210	
WAC	WAC 284-43-2050	
RCW		
Contract Citation	☒ WAH	AH section 17.3.2.1 General Description of Contracted Services - Pharmacy Benefit and Services - Apple Health Preferred Drug List and Plan Formularies
	☒ IMC	IMC section 16.12.2 General Description of Contracted Services - Pharmacy Benefit and Services - Apple Health Preferred Drug List and Plan Formularies
	☒ MA	
Other Requirements		
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
07/24/2017	*NEW*	Michael Sporck, Pharmacy Intern Sophia Yun, PharmD
07/25/2017	Approval	MMLT
03/09/2018	Reassigned from UM to PM	Cindy Bush
04/25/2018	Revised	Jennifer Farley PharmD
05/14/2018	Revised, added HTA/LCD box	Catherine Vu, PharmD
11/27/2018	Updated LCD reference	Jennifer Farley PharmD
12/12/2018	Approval	UM Committee
03/01/2019	Revised (addition of new product)	Jennifer Farley PharmD
03/14/2019	Approval	UM Committee
09/06/2019	Removed reference to Local Coverage Article as it should not be used as critera.	Jennifer Farley PharmD
09/12/2019	Approval	UM Pharmacy Subcommittee