SENTARA HEALTH PLANS

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

<u>Directions:</u> The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; <u>fax to 1-844-668-1550</u>. No additional phone calls will be necessary if all information (<u>including phone and fax #s</u>) on this form is correct. <u>If information provided is not complete</u>, correct, or legible, authorization can be delayed.

<u>For Medicare Members:</u> 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: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Hyaluronate Acids (Medical)

PREFERRED

Drug Requested: (check box below that applies)

□ Euflexxa®(J7323)			 □ Synvisc® (J7325) □ Synvisc-One® (J7325) 			
		NON-PR	EFER	RRED		
	Durolane® (J7318)	□ Gel-One® (J7326)		□ Gel-Syn® (J7328)	□ Genvisc 850® (J7320/Q9980)	
	Hyalgan® (J7321)	□ Hymovis® (J7322/C9- (NDC 89122-0496-63)	471)	□ Orthovisc® Injections (J7324)	□ Monovisc® (J7327)	
	Supartz®/FX (J7321)	□ SynoJoynt [™] (J7331)		□ Triluron® (J7332)	□ TriVisc® (J7329)	
	Visco-3 [™] (J7321)					
MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.						
Me	mber Name:					
	Member Name:					
Prescriber Name:						
Prescriber Signature:			Date:			
Off	Office Contact Name:					
Phone Number:			Fax Number:			
NPI #:						

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DRUG INFORMATION: Authorization may be delayed if incomplete.				
Drug Name/Form/Strength:				
Dosing Schedule:	Length of Therapy:			
Diagnosis:	ICD Code, if applicable:	_		
Weight (if applicable):	Date weight obtained:	_		

□ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Coverage Exclusions:

- Intra-articular injections of sodium hyaluronate are unproven and <u>NOT</u> medically necessary for treating any other indication due to insufficient evidence of efficacy including, but not limited to the following:
 - Hip osteoarthritis
 - Temporomandibular joint osteoarthritis
 - o Temporomandibular joint disc displacement
 - Joint Replacement There are no clinical trials evaluating the use of sodium hyaluronate in persons following total or partial joint replacement surgery
 - Patellofemoral syndrome, post-anterior cruciate ligament [ACL] reconstruction)
- Hyaluronic acid gel preparations to improve the skin's appearance, contour and/or reduce depressions due to acne, scars, injury or wrinkles are considered cosmetic and are **NOT** covered
- Hyalgan[®], Synvisc[®], Synvisc-One[®], Supartz[®], Euflexxa[®], Gel-One[®], Orthovisc[®], Gel-Syn[®], Genvisc[®] and Durolane[®] coverage is <u>EXCLUDED</u> in members with <u>bone-on-bone</u> (no cartilage present) pain
- Synvisc–One[®] is limited to **ONE** office visit

Dosing Limits:

Drug	1 Billable Unit (BU)	# of BU per Injection	Injections per knee (per 180 days)	Injections both knees (per 180 days)	Max units per knee (per 180 days)
Euflexxa 20 mg/2 mL injection	1 dose	1	3	6	3
Durolane 60 mg/3 mL injection	1 mg	60	1	2	60
Gel-One 30 mg/3 mL injection	1 dose	1	1	2	1
GelSyn-3 16.8 mg/2 mL injection	0.1 mg	168	3	2	504
GenVisc 850 25mg/3 ml injection	1 mg	25	5	10	125
Hyalgan 20 mg/2 mL injection	1 dose	1	5	10	5
Hymovis 24 mg/3 mL injection	1 mg	24	2	4	48

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Drug	1 Billable Unit (BU)	# of BU per Injection	Injections per knee (per 180 days)	Injections both knees (per 180 days)	Max units per knee (per 180 days)
Monovisc 88 mg/4 mL injection	1 dose	1	1	2	1
Orthovisc 30 mg/2 mL injection	1 dose	1	4	8	4
Supartz 25 mg/2.5 mL injection	1 dose	1	5	10	5
Supartz FX 25 mg/2.5 mL injection	1 dose	1	5	10	5
SynoJoynt 20 mg/2 mL injection	1 dose	20	3	6	60
Synvisc 16 mg/2 mL injection	1 mg	16	3	6	48
Synvisc-One 48 mg/6 mL injection	1 mg	48	1	2	48
Triluron	1 mg	20	3	6	60
Trivisc	1 mg	25	3	6	75
VISCO-3	1 dose	1	3	6	3

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

☐ Member has tried and failed both Euflexxa® AND Synvisc® or Synvisc-One®

□ For Osteoarthritis (OA) indications □ Member has a diagnosis of Osteoarthritis of the: □ Left knee and/or □ Right knee AND

- ☐ Member has had a trial and failure to <u>BOTH</u> of the following conservative methods which has not resulted in functional improvement after at least three (3) months:
 - □ Non-Pharmacologic (i.e. physical, psychological or mind -body approach [e.g. exercise-land based or aquatic, physical therapy, tai chi, yoga, weight management, cognitive behavioral therapy, knee brace or cane])
 - ☐ Pharmacologic approach (e.g., oral/topical NSAIDs, with or without oral proton pump inhibitors, COX-2 inhibitors, topical capsaicin, acetaminophen, tramadol, duloxetine)

AND

☐ Member has failed to adequately respond to aspiration and injection of intra-articular steroids

AND

☐ Member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing)

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References:

American College of Rheumatology (ACR)

• In its published "Recommendations for the Use of Nonpharmacologic and Pharmacologic Therapies in Osteoarthritis of the Hand, Hip, and Knee," the ACR makes both "strong" and "conditional" recommendations for OA management. The ACR states that in OA generally, IA glucocorticoid injection is conditionally recommended over other forms of IA injection, including hyaluronic acid preparations. Head-to-head comparisons are few, but evidence for efficacy of glucocorticoid injections were considerably higher quality than that of other agents. They also stated that IA hyaluronic acid injections are conditionally recommended against in patients with knee and/or first CMC joint OA, as best evidence failed to establish a benefit, and that harm may be associated with these injections. However, as many providers want the option of using hyaluronic acid injections when other interventions fail to adequately control local joint symptoms in clinical practice, the ACR recommends that using hyaluronic acid may be viewed more favorably than offering no intervention, and therefore may be used in the context of shared decision-making that recognizes the limited evidence of benefit of this treatment. In contrast, the ACR strongly recommended against use in patients with hip OA due to higher quality evidence of lack of benefit (2020).

American Academy of Orthopaedic Surgeons (AAOS)

• In their 2nd edition evidence-based guideline titled "Treatment of Osteoarthritis of the Knee," the AAOS does not support the use of viscosupplementation for treatment of knee OA. This rationale is based on limitations in the literature which include variable quality of studies, a large degree of heterogeneity in outcomes, and possible publication bias (2013)

Medication being provided by (check box below that applies):				
☐ Location/site of drug administration:				
NPI or DEA # of administering location:				
OR				
☐ Specialty Pharmacy – Proprium Rx				

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.