Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Hyaluronic Acid Injection for Knee Osteoarthritis		
MNG #: 58	**☒SCO ☒One Care** **☒ MAPD-MA Medicare Preferred** **☒ MAPD-MA Medicare Value** **☒ MAPD-RI Medicare Preferred** **☒ MAPD-RI Medicare Value** **☒ DSNP-RI Medicare Maximum**	**Prior Authorization Needed?** **☐Yes ☐No**
Clinical: ☒	**Operational: ☐**	**Informational: ☐**
Medicare Benefit: **☐Yes ☐No**	**Approval Date:** 2/4/2021	**Effective Date:** 05/22/2021
Last Revised Date:	**Next Annual Review Date:** 02/04/2022	**Retire Date:**

OVERVIEW: Osteoarthritis (OA) is a complex pathophysiologic process that involves subchondral bone, synovium, and periarticular structures. OA-related joint pain is a common condition that can limit activity, while also having an affect on mental health and sleep (1). Viscosupplementation using hyaluronic acid (HA) knee injections is a treatment that has been approved by the FDA for the treatment of pain associated with knee OA in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics.

This CCA Medical Necessity Guideline outlines medical necessity requirements for approval of HA derivatives for knee OA. HA drugs are a class that has CCA preferred alternatives. CCA preferred HA derivatives include: Durolane, Euflexxa, Gelysn-3, and Supartz. For non-preferred medical benefit HA derivatives, additional step therapy requirements apply and can be found at MNG 040 Medicare Part B Step Therapy.

Clinical Coverage Criteria: CCA may authorize the coverage of in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics. Clinical documentation must accompany the authorization request that clearly documents that the member has met all of the following criteria:

Initial Approval:

1. A documented diagnosis of knee OA by either:
    a. Diagnosis of knee OA by either:
        i. Radiographic evidence of OA including joint space narrowing, subchondral sclerosis, osteophytes and subchondral cysts (Kellgren-Lawrence Scale grade 3 or higher)
        ii. Clinical documentation of moderate to severe OA with five (5) or more of the following signs and symptoms:
            1. Crepitus
            2. Bony enlargement
            3. Bony tenderness
            4. Erythrocyte sedimentation rate (ESR) less than 40 mm/hr

Medical Necessity Guideline

5. Less than 30 minutes of morning stiffness
6. No palpable warmth of synovium
7. 50 years of age or older
8. Rheumatoid factor less than 1:40 titer (agglutination method)
9. Synovial fluid signs (clear fluid of normal viscosity and white blood cells less than 2000, mm^3)

2. OA-related knee pain is significantly affecting functional activities (e.g.; ambulation or prolonged standing). Pain cannot be attributed to other forms or locations of joint pain.
3. The prescribing provider is a rheumatologist, orthopedic specialist, physiatrist, or sports medicine specialist
4. The Member has demonstrated an inadequate response, contraindication or inability to tolerate **all** of the following conservative therapies:
   - Exercise program, weight loss (if the member is overweight), and physical therapy
   - Inadequate response to a trial of analgesic therapy such as: non-steroidal anti-inflammatory drugs (NSAIDS), acetaminophen (at least 3 grams per day), and/or topic capsaicin cream). Inadequate response is defined as failing to provide functional activity improvement after, at a minimum, 3 months of treatment. If a specific analgesic therapy is contraindicated, there must be clear documentation of the reason.
   - Inadequate response or intolerance/contraindication to intraarticular corticosteroid injection for at least 3 months. If a specific analgesic therapy is contraindicated, there must be clear documentation of the reason.

Note: Initial authorization is limited to one treatment course as outlined in Table 1.

Table 1. Treatment course by Hyaluronic Acid Derivative

	Hyaluronic Acid Product	Course of Treatment
Preferred	Durolane	1 injection
	Euflexxa	3 injections
	Gelsyn-3	3 injections
	Supartz	3-5 injections
Non-Preferred	Gel One	1 injection
	GenVisc 850	3-5 injections
	Hyalgan	5 injections
	Hymovis	2 injections
	Monovisc	1 injection
	Orthovisc	3-4 injections
	Synojoynt	3 injections
	Synvisc	3 injections
	Synvisc One	1 injection
	Triluron	3 injections
	Trivisc	3 injections
	VISCO-3	3 injections

Reapproval

Medical Necessity Guideline

CCA may approve additional courses of the preferred HA derivatives (Durolane, Euflexxa, Gelysn-3, and Supartz) when all of the following criteria are met and clear clinical documentation is provided with the request:

1. The medical necessity criteria for initial approval continue to be met
2. Significant improvement in pain of ≥50% after completion of initial HA course
3. Reduction in analgesic therapy (i.e. NSAIDs, acetaminophen, and/or topical capsaicin cream) use in the 3-month period immediately following completion of the initial HA treatment course.
4. Improvement in activity level and function.
5. At least six (6) months have lapsed since the completion of the prior HA derivative treatment course

Note: Each reauthorization is limited to one (1) additional treatment course as outlined in Table 1.

LIMITATIONS/EXCLUSIONS:

1. HA derivatives are only approved for knee OA and not for other joints. Requests for HA injections to other joints are considered experimental and are not covered by CCA per criteria outlined in CCA MNG 010 Experimental and Investigational Services.
2. HA derivatives are not covered for isolated patella femoral arthritis or patella femoral syndrome as this is considered experimental per criteria outlined in CCA MNG 010 Experimental and Investigational Services.
3. Ultrasound guidance, fluoroscopic guidance, and knee arthrography for knee injections, including for HA derivative administration, are considered experimental and are therefore not covered by CCA per criteria outlined in CCA MNG 010 Experimental and Investigational Services (hyperlink here).
4. Requests for CCA non-preferred HA derivatives must meet criteria for medical necessity as outlined in this MNG and are also subject to step therapy requirements as outlined in MNG 040 Medicare Part B Step Therapy.
5. Requests for reauthorization of any HA derivative after the initial 12-month course must clinical documentation indicating sustained effectiveness

RELATED REFERENCES:

1. Neogi T. The epidemiology and impact of pain in osteoarthritis. Osteoarthritis Cartilate. 2013;21(9):1145-53
2. Newberry SJ, Fitzgerald JD, Maglione MA et al. Systematic Review for Efectiveness of Hyaluronic Acid in the Treatment of Severe Degenerative Joint Disease (DJD) of the Knee. AHRQ Technology Assessment Program. Released 7/23/2015.
3. Local Coverage Article: Billing and Coding: Hyaluronans Intra-articular Injections (A52420). https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=55036&ver=52&KeyWord=hyaluron&KeyWordLookUp=Title&KeyWordSearchType=Exact&bc=CAAAAAAAAAAA. Accessed 1/14/2021.

Medical Necessity Guideline

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

Click here to enter text.	
CCA Senior Clinical Lead [Print]	**Title [Print]**
Signature	**Date**
Doug Hsu, MD	VP, Medical Policy & Utilization Review
CCA Senior Operational Lead [Print]	**Title [Print]**
	3/4/2021
Signature	**Date**
Lori Tishler, MD	SVP, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
	3/4/2021
Signature	**Date**