



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 02/21/19
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

INTRA-ARTICULAR HYALURONAN INJECTIONS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

Description:

Intra-articular injection of hyaluronan (HA) into osteoarthritic joints is thought to replace HA, restore the viscoelastic properties of the synovial fluid and improve pain and function.

Preferred Intra-Articular Hyaluronan Injections:

- Durolane® (Hyaluronic acid)
- Gelsyn-3™ (Sodium Hyaluronate 0.84%) also known as Gel-Syn™
- Monovisc® (Sodium hyaluronate)
- OrthoVisc® (Hyaluronan, Sodium hyaluronate)
- Supartz FX™ (Sodium hyaluronate) formerly Supartz®
- Synvisc® (Hylan, Hylan GF 20)
- Synvisc-One® (Hylan G-F 20)

Non-Preferred Intra-Articular Hyaluronan Injections:

- Euflexxa® (1% Sodium hyaluronate)
- Gel-One® (Hyaluronan hydrogel)
- GenVisc 850® (Sodium hyaluronate)
- Hyalgan® (Sodium hyaluronate)
- Hymovis® High Molecular Weight Viscoelastic Hyaluronan
- Visco-3™ (Sodium hyaluronate)

Definitions:

Osteoarthritis:

Degenerative joint disease that occurs when the cartilage in joint wears down and the bone surfaces rub against each other. Also referred to as degenerative arthritis or inflammatory osteoarthritis.

Chondromalacia Patella:

Softening and degeneration of the cartilage underneath the kneecap. May be considered a form of osteoarthritis.



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INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

Criteria:

- Initial course of **preferred** intra-articular hyaluronan injections for treatment of painful osteoarthritis of the knee is considered **medically necessary** with documentation of **ALL** of the following:
 1. Failure to respond to at least 3 months of conservative treatment (e.g., exercise, physical therapy, activity modification, knee bracing, analgesics, topical capsaicin cream, nonsteroidal anti-inflammatories, unless otherwise clearly documented as contraindicated)
 2. Failure to respond to aspiration and injection of intra-articular steroids
 3. Pain which interferes with functional activities (e.g., ambulation, prolonged standing) and the pain cannot be attributed to other forms of joint disease
 4. Total knee replacement is not scheduled within 6 months of starting treatment
 5. Course of treatment is **ONE** of the following:
 - Weekly injections for 3-5 weeks with Supartz FX
 - Weekly injections for 3-4 weeks with OrthoVisc
 - Weekly injections for 3 weeks with GELSYN-3 (Gel-Syn) or Synvisc
 - One injection of Durolane, Synvisc-One or Monovisc
- If above criteria not met, initial course of **preferred** intra-articular hyaluronan injections for treatment of painful osteoarthritis of the knee is considered **not medically necessary**.
- Repeat course of **preferred** intra-articular hyaluronan injections for recurrence or worsening of pain due to osteoarthritis of the knee is considered **medically necessary** with documentation of **ALL** of the following:
 1. Positive response to the prior course of injections with documentation of **ALL** of the following:
 - Significant pain relief achieved
 - Improved range of motion (ROM) and function
 - Improvement or maintenance of activities of daily living (ADLs)
 2. Minimum of 6 months has elapsed since completion of the previous course of treatment
 3. Total knee replacement is not scheduled within 6 months of starting treatment
 4. Course of treatment is **ONE** of the following:
 - Weekly injections for 3-5 weeks with Supartz FX
 - Weekly injections for 3-4 weeks with OrthoVisc
 - Weekly injections for 3 weeks with GELSYN-3 (Gel-Syn) or Synvisc
 - One injection of Durolane, Synvisc-One or Monovisc
- If above criteria not met, repeat course of **preferred** intra-articular hyaluronan injections for recurrence or worsening of pain due to osteoarthritis of the knee is considered **not medically necessary**.



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INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

Criteria: (cont.)

- Initial course of **non-preferred** intra-articular hyaluronan injections for treatment of painful osteoarthritis of the knee is considered **medically necessary** with documentation of **ALL** of the following:
 1. Failure to respond to at least 3 months of conservative treatment (e.g., exercise, physical therapy, activity modification, knee bracing, analgesics, topical capsaicin cream, nonsteroidal anti-inflammatories, unless otherwise clearly documented as contraindicated)
 2. Failure to respond to aspiration and injection of intra-articular steroids
 3. Pain which interferes with functional activities (e.g., ambulation, prolonged standing) and the pain cannot be attributed to other forms of joint disease
 4. Total knee replacement is not scheduled within 6 months of starting treatment
 5. Failure of, contraindication to or intolerance to **ONE** of the preferred intra-articular hyaluronan injections Durolane, Gelsyn-3 (Gel-Syn), Monovisc, Orthovisc, Supartz FX, Synvisc or Synvisc-One.
 6. Course of treatment is **ONE** of the following:
 - Weekly injections for 3-5 weeks with GenVisc 850 or Hyalgan
 - Weekly injections for 3 weeks with Euflexxa or Visco-3
 - Weekly injections for 2 weeks with Hymovis
 - One injection of Gel-One
- If above criteria not met, initial course of **non-preferred** intra-articular hyaluronan injections for treatment of painful osteoarthritis of the knee is considered **not medically necessary**.



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INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

Criteria: (cont.)

- Repeat course of **non-preferred** intra-articular hyaluronan injections for recurrence or worsening of pain due to osteoarthritis of the knee is considered **medically necessary** with documentation of **ALL** of the following:
 1. Positive response to the **non-preferred** intra-articular hyaluronan injections used in the initial or prior course with documentation of **ALL** of the following:
 - Significant pain relief achieved
 - Improved range of motion (ROM) and function
 - Improvement or maintenance of activities of daily living (ADLs)
 2. Minimum of 6 months has elapsed since completion of the previous course of treatment
 3. Total knee replacement is not scheduled within 6 months of starting treatment
 4. Failure of, contraindication to or intolerance to **ONE** of the preferred intra-articular hyaluronan injections Durolane, Gelsyn-3 (Gel-Syn), Monovisc, Orthovisc, Supartz FX, Synvisc or Synvisc-One.
 5. Course of treatment is **ONE** of the following:
 - Weekly injections for 3-5 weeks with GenVisc 850 or Hyalgan
 - Weekly injections for 3 weeks with Euflexxa or Visco-3
 - Weekly injections for 2 weeks with Hymovis
 - One injection of Gel-One
- If above criteria not met, repeat course of **non-preferred** intra-articular hyaluronan injections for recurrence or worsening of pain due to osteoarthritis of the knee is considered **not medically necessary**.
- Greater than 6 courses of treatment per knee will be reviewed by the medical director(s) and/or clinical advisor(s).



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Criteria: (cont.)

- Intra-articular hyaluronan injections for all indications other than osteoarthritis of the knee are considered ***experimental or investigational*** based upon:
1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to*:

- Pain in partial or total artificial knees
- Any joint other than the knee
- Treatment with dosing or frequency outside the FDA-approved dosing and frequency

Resources:

Literature reviewed 07/05/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 2.01.31 BCBS Association Medical Policy Reference Manual. Intra-articular Hyaluronan Injections for Osteoarthritis. Re-issue date 04/12/2018, issue date 07/10/1998.
2. Altman, R, Moskowitz, R. Intraarticular Sodium Hyaluronate (Hyalgan) in the Treatment of Patients With Osteoarthritis of the Knee: A Randomized Clinical Trial. *J Rheumatol*. 1998;25:2203-2212.
3. American Academy of Orthopaedic Surgeons (AAOS). Treatment of Osteoarthritis of the Knee 05/18/2013; 2nd Edition.
4. BCBS Association. Special Report: Intra-Articular Hyaluronan Injections for the Treatment of Osteoarthritis of the Knee. 06/02/2004.
5. BCBS Association Technology Assessment Program. Special Report: Intra-Articular Hyaluronan Injections for the Treatment of Osteoarthritis of the Knee. 02/2005.



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Resources: (cont.)

6. Bragantini, A, Cassini, M, et, al. Controlled Single-Blind Trial of Intra-Articularly Injected Hyaluronic Acid (Hyalgan) in Osteo-Arthritis of the Knee. *Clinical Trials Journal*. 1987 1987;24(No 4):333-340.
7. California Technology Assessment Forum. Hyaluronic Acid for Treatment of Osteoarthritis of the Knee: Repeated Injections and Progression to Knee Replacement. 02/08/2012.
8. External Consultant Review. Orthopedic. 05/31/2005.
9. External Consultant Review. Orthopedic. 03/28/2005.
10. External Consultant Review. Orthopedic Surgery. 02/27/2008.
11. External Consultant Review. Orthopedic. 10/2006.
12. External Consultant Review. Orthopedic Surgery. 10/2006.
13. Lo GH, LaValley M, McAlindon T, Felson DT. Intra-articular hyaluronic acid in treatment of knee osteoarthritis: a meta-analysis. *JAMA*. Dec 17 2003;290(23):3115-3121.
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15. Pritchard, C, Sripada, P, et, al. A Retrospective Comparison of the Efficacy and Tolerability of Sodium Hyaluronate and Hylan G-F 20 in the Treatment of Osteoarthritis of the Knee. *Journal of Musculoskeletal Research*. 2002;6(3 & 4):197-205.
16. Raynauld, J, Goldsmith, C, et, al. Effectiveness and Safety of Repeat Courses of Hylan G-F 20 in Patients With Knee Osteoarthritis. *OsteoArthritis and Cartilage*. 2005;13:111-119.
17. Scali, J. Intra-Articular Hyaluronic Acid in the Treatment of Osteoarthritis of the Knee: A Long Term Study. *European Journal of Rheumatology and Inflammation*. 1995;15.
18. Waddell, DD, Cefalu, C, et, al. An Open-Label Study of a Second Course of Hylan G-F 20 for the Treatment of Pain Associated With Knee Osteoarthritis. *Curr Med Res Opin*. 2003;19(6):499-507.
19. Wang CT, Lin J, Chang CJ, Lin YT, Hou SM. Therapeutic effects of hyaluronic acid on osteoarthritis of the knee. A meta-analysis of randomized controlled trials. *J Bone Joint Surg Am*. 2004 Mar 2004;86-A(3):538-545.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilínígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowolgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

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Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はいかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید، سوال در مورد Blue Cross Blue Shield of Arizona، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید].

Assyrian:

Blue Cross Blue Shield of Arizona دەوڵەتی ئێرانە، و ئێمە ئێوەوە ئازاد دەکەین. Blue Cross Blue Shield of Arizona دەوڵەتی ئێرانە، و ئێمە ئێوەوە ئازاد دەکەین. 877-475-4799

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณต้องการช่วยเหลือสอบถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์ที่จะได้รับความช่วยเหลือและข้อมูลในภาษา ของคุณได้โดยไมมีค่าใช้จ่าย ติดต่อสอบถาม โทร 877-475-4799