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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.
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:
- 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)
- Hylgan® (Sodium hyaluronate)
- Hymovis® High Molecular Weight Viscoelastic Hyaluronan

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.

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

Significant Adverse Drug Event:
A significant adverse drug event occurs when an individual’s outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals’ body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.
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 Synvisc-One or Monovisc

- 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 Synvisc-One or Monovisc
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-inflammatory, 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. Failed response to **ONE** of the preferred intra-articular hyaluronan injections Gelsyn-3 (Gel-Syn), Monovisc, Orthovisc, Supartz FX, Synvisc or Synvisc-One (unless otherwise contraindicated or not labeled for the indication being prescribed) with documentation of **ANY** of the following:
    - Individual’s condition has not improved or has worsened
    - Individual experienced a significant adverse drug event to the preferred intra-articular hyaluronan injections
    - Individual is intolerant to the preferred intra-articular hyaluronan injections
    - Individual is non-adherent to the preferred intra-articular hyaluronan injections
    - Individual has a medical condition(s) that prevents use of the preferred intra-articular hyaluronan injections (e.g., the preferred intra-articular hyaluronan injections are contraindicated for use with the medical condition)

  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
    - Weekly injections for 2 weeks with Hymovis
    - One injection of Gel-One
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. Failed response to ONE of the preferred intra-articular hyaluronan injections Gelsyn-3 (Gel-Syn), Monovisc, Orthovisc, Supartz FX, Synvisc or Synvisc-One (unless otherwise contraindicated or not labeled for the indication being prescribed) with documentation of ANY of the following:
   • Individual’s condition has not improved or has worsened
   • Individual experienced a significant adverse drug event to the preferred intra-articular hyaluronan injections
   • Individual is intolerant to the preferred intra-articular hyaluronan injections
   • Individual is non-adherent to the preferred intra-articular hyaluronan injections
   • Individual has a medical condition(s) that prevents use of the preferred intra-articular hyaluronan injections (e.g., the preferred intra-articular hyaluronan injections are contraindicated for use with the medical condition)

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
   • Weekly injections for 2 weeks with Hymovis
   • One injection of Gel-One

➢ Greater than 6 courses of treatment per knee will be reviewed by the medical director(s) and/or clinical advisor(s).
INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

Criteria: (cont.)

- Intra-articular hyaluronan injections for all other indications not previously listed or if above criteria not met 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 05/09/17. 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.


INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

Resources: (cont.)


12. FDA. Gel-One. 03/22/2011.


INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

Resources: (cont.)


INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

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 niilíígií Blue Cross Blue Shield of Arizona haadá yit’éego bíína’ídleéjígo éí doodago Háída bíí jááníyeeéígíí tááddoo le’í yína’ídleéjígo beehaz’áánii hóló díí t’áá házadd’ék’ehí háká a’doowolgo bebe haz’a doo baq’á ilínígóó. Atá’ halne’ígíí kójí bíchí’í jí hodíílíhn 877-475-4799.

Chinese: 如果您, 或您正在協助的對象, 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 thống dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعدة أسلحة بخصوص تلك الأسلحة غير البالغين، يرجى الاتصال ب告诉我们 للحصول على المساعدة والمعلومات باللغة العربية. Blue Cross Blue Shield of Arizona 877-475-4799.
INTRA-ARTICULAR HYALURONAN INJECTIONS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tunawiang, ay may mga katarungan tungkol sa Blue Cross Blue Shield of Arizona, may kaparalan na makakahalal at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하는 다음을 알고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관련된 질문이 있다면 귀하의 물질과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 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:

آگر شما یا کسی که شما به او کمک می‌کنید، سوالی در مورد اطلاعاتی باشد که به موارد مختلف Blue Cross Blue Shield of Arizona مربوط کرده‌باشد، لطفاً به تلفن 877-475-4799 تماس حاصل نمایید.

Assyrian:

, ناشقو یا مسایله‌دارانی با کمک Blue Cross Blue Shield of Arizona می‌توانند در مورد سوالات خود با تلفن 877-475-4799 تماس بگیرند.

Serbo-Croatian: Ukoiko 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 หรือคุณท่านใดมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถได้รับความช่วยเหลือและข้อมูลภาษา ของคุณได้โดยไม่เสียค่าใช้จ่าย ตลอดเวลา โทร 877-475-4799