Intra-articular Hyaluronan Injections for Osteoarthritis

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required. *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

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. The majority of studies to date have assessed HA injections for knee osteoarthritis, and this is the U.S. Food and Drug Administration (FDA) approved indication. Other joints, such as the hip and shoulder, are currently being investigated for intra-articular HA treatment of osteoarthritis (OA).

Hyaluronan (HA) is a naturally occurring macromolecule that is a major component of synovial fluid and is thought to contribute to its viscoelastic properties. Chemical crosslinking of hyaluronan increases its molecular weight; crosslinked hyaluronans are referred to as hylans. In osteoarthritis (OA), the overall length of HA chains present in cartilage and the HA concentration in the synovial fluid are decreased. Intra-articular injection of HA (IAHA) has been proposed as a means of restoring the normal viscoelasticity of the synovial fluid in patients with OA. This treatment has been called viscosupplementation.

Six preparations of intra-articular (IA) hyaluronan have been approved by the FDA as an alternative to nonsteroidal anti-inflammatory drug therapy in the treatment of OA of the knee (Synvisc® and Synvisc-One®, Genzyme; Hyalgan®, Fidia; Supartz®, Smith and Nephew; OrthoVisc®, Anika; and Euflexxa®, previously named Nuflexxa, Savient). All products are manufactured from rooster combs except for Euflexxa and Orthovisc, which are produced from bacterial fermentation. Also, Synvisc undergoes additional chemical crosslinking to create hylans with increased molecular weight (6,000 kDa) compared to Hyalgan (500-730 kDa) and Supartz (620-1170 kDa). The differing molecular weights of the products lead to different half-lives; the half-life of Hyalgan or Supartz is estimated at 24 hours, while the half-life of Synvisc may range up to several days.

Currently, no curative therapy is available for OA, and thus the overall goals of management are to reduce pain and prevent disability. Intra-articular hyaluronic acid is “indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy, and to simple analgesics, e.g., acetaminophen.” The product inserts further indicate that Synvisc® and Euflexxa® should be injected intra-articularly into the knee joint once per week for a total of three injections over a two- to three-week period. In contrast, five weekly injections are recommended for the Hyalgan® and Supartz® products, and three to four weekly injections are recommended for OrthoVisc®. In February 2009, the FDA approved the use of single-dose hylan G-F 20 (Synvisc-One™) for the treatment of OA of the knee.

In 2000, the FDA approved removal of a precautionary statement from the package inserts for Hyalgan and Synvisc that stated that the safety and efficacy of repeat courses have not been established.

The FDA has not approved intra-articular hyaluronan for joints other than the knee.
Related Protocols:
Electrical Stimulation for the Treatment of Arthritis
Temporomandibular Joint Dysfunction
Arthroscopic Debridement and Lavage as Treatment for Osteoarthritis of the Knee

Corporate Medical Guideline
Intra-articular hyaluronan injections may be considered medically necessary for treatment of painful osteoarthritis of the knee in patients who have insufficient pain relief from conservative nonpharmacologic therapy and simple analgesics.

Repeated courses of intra-articular hyaluronan injections of the knee may be considered medically necessary under the following conditions:

- Significant pain relief achieved with the prior course of injections; and
- At least six months have passed since completion of the prior course.

The use of intra-articular hyaluronan injections in joints other than the knee is considered investigational.

Policy Guideline
Appropriate candidates for hyaluronan injections are those who have failed conservative therapy with nonsteroidal anti-inflammatory drugs (NSAIDs) or who have contraindications to NSAID therapy. Plans may also require candidates for hyaluronan injections to have failed intra-articular injections of corticosteroids.

A course of hyaluronan injections is defined according to labeled indications for each product; one formulation involves a single injection, others use multiple injections. For example, Synvisc-One® is a single 6-mL injection treatment regimen. For a single course of treatment, the single injection formulation should not be followed with subsequent doses of the multiple-injection formulations.

When determining the timing of repeated courses, the prior course is assumed to have been completed at the date of the last injection of the series of injections.

Medicare Advantage
Viscosupplementation with hyaluronans may be considered medically necessary for osteoarthritis of the knee or shoulder joint when:

- There is radiological evidence to support the diagnosis of osteoarthritis; and
- There is adequate documentation that simple pharmacologic therapy (e.g., aspirin), or exercise and physical therapy has been tried and the patient has failed to respond satisfactorily.

The following products have received FDA approval:

- Hylan G-F 20 (Synvisc®), given once weekly for a total of three weeks.
- Hylan G-F 20 (Synvisc-One™), given once per six months and limited to osteoarthritis of the knee.
- Sodium hyaluronate (Hyalgan®, Supartz®, Euflexxa™)
  - Hyalgan® and Supartz®, given once weekly for a total of five injections (Hyalgan) or five weeks (Supartz®)
  - Euflexxa™, device indicated for a three-injection treatment regimen.
- High molecular weight Hyaluronan (Orthovisc®), administered weekly for three-four weeks.
- Hyaluronic acid (Gel-One®), intra-articular injections of the knee.

A one-time repeat series of injections for patients who have responded to the first series may be given individual consideration for coverage provided that the drug is administered in accordance with FDA-approved indications and under the following circumstances:

- Significant improvement in knee or shoulder pain and known improvement in functional capacity resulted from the first series of injections which has been documented in the record; and

- At least six (6) months have elapsed since the prior series of injections.

If the drug is denied as not medically necessary, the associated injection code will also be denied.

Additional repeat treatments are considered medically necessary for patients being treated for osteoarthritis of the knee, who meet both of the following criteria:

- Significant improvement in knee pain and known improvement in functional capacity resulted from the previous series of injections which has been documented in the record; and

- At least six (6) months have elapsed since the prior series of injections.

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


46. NGS, Inc. Local Coverage Article for Hyaluronans (e.g.,Hyalgan®, Supartz®, Euflexxa™, Synvisc®, Synvisc-One™, Orthovisc®, Gel-One® ), Intra-articular Injections of - Related to LCD L25820 (A46100), 08/20/2012.