SODIUM HYALURONATE
RX501.049
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COVERAGE:

Sodium Hyaluronate (Hyaluronan, Hylan G-F20, Hylan Gel-Fluid, Hyalgan, Supartz, Synvisc) intra-articular injections is considered medically necessary as either a single treatment cycle or a course of repeated treatment cycles for the treatment of patients with painful osteoarthritis of the knee who have insufficient pain relief from conservative nonpharmacologic therapy and simple analgesics (e.g., acetaminophen).

Sodium Hyaluronate (Hyaluronan, Hylan G-F20, Hylan Gel-Fluid, Hyalgan, Supartz, Synvisc) intra-articular injections for the treatment of OTHER joints (e.g., the shoulder or hip) are considered experimental or investigational.

Note: See policy description for the definition of treatment cycles and repeated treatment cycles.

Sodium Hyaluronate (Staarvisc) is considered medically necessary for use during surgery in the anterior and posterior chambers of the eye.

DESCRIPTION:

Sodium Hyaluronate (SH), similar to hyaluronic acid, is a sticky (viscous) elastic solution (approved by the FDA as a medical device), which is injected into a knee joint to ease the pain from osteoarthritis. In addition, SH has been approved by the FDA for use during intraocular surgery.

SH penetrates the articular cartilage surface, the synovial tissue, and the capsule of the joints. In the normally functioning joint, the hyaluronic acid (a normal element of synovial fluid in the human joint) lubricates the joint during low impact activities, such as resting or walking. During high impact activities, such as running, hyaluronic acid helps to prevent mechanical damage and decrease shock on the joint.

There are many types of arthritis (rheumatoid, degenerative, post-traumatic, autoimmune induced, etc.). The most common form is osteoarthritis, also known as degenerative joint disease. While the exact cause is unknown, there are several possible causes, including injury, age, congenital predisposition, and obesity. In patients with osteoarthritis, the elasticity and viscosity of the synovial fluid and the hyaluronic acid concentration are reduced, and this is characterized by the breakdown of the articular cartilage within the joint. This causes a reduction of the protective, lubricating, and shock absorbing properties of the synovial fluid. By injecting hyaluronic acid (SH) into the joint, known as visco-supplementation or intra-articular injection, the normal environment of the synovial fluid is restored. Currently, there is no curative therapy for osteoarthritis, and thus the overall goals of management are to reduce
pain and prevent disability.

SH, used as an injectable for the knee joint, is currently marketed as Hyalgan, Supartz, or Synvisc.

- The FDA approved Hyalgan in May 1997 for use as a medical device, not as a drug classification, to treat the pain in osteoarthritis of the knee. The use of Hyalgan for treatment in shoulder or hip joints is still undergoing clinical trials.

- The FDA approved Synvisc Hylan G-F20 in August 1997 as a medical device, not as a drug classification, to treat the pain of an osteoarthritic knee.

- The FDA approved Supartz in January 2001 as a medical device, not as a drug classification, to relieve pain from osteoarthritis of the knee joint.

For all three devices, the patient must have failed to respond adequately to conservative therapy. This includes, but is not limited to, simple pain relievers, exercise, and physical therapy.

Treatment Cycles:

- The product inserts indicate that the Synvisc product should be injected intra-articularly into the knee joint once weekly. Relief may last up to six months or longer.
- In contrast, five weekly injections are recommended for the Hyalgan product. Relief may last up to twelve months.
- The product insert for Supartz states that most patients will experience less pain after five weekly injections. In each situation, the series of injections is considered a treatment cycle.

In 2000, the FDA approved revised labeling for Hyalgan by deleting the statement on multiple or repeated treatment cycles. However, the Synvisc labeling remains unchanged.

In April 2001, the FDA approved Staarvisc Sodium Hyaluronate to act as a tissue lubricant and also to maintain the volume of eye fluid during surgery on the inside of the eye. In the ocular setting, SH is similar to the natural fluid of the eye. Staarvisc is used for procedures involving the anterior and posterior chambers of the eye, such as:

- Cataract extraction,
- Intraocular lens (IOL) implantation,
- Corneal transplantation surgery,
- Glaucoma filtering surgery, and
- Retinal reattachment procedures.
Once the procedure has been completed, Staarvisc is removed from the anterior chamber to prevent or minimize post-operative intraocular pressure increases.

RATIONALE:

The quality of the evidence from randomized controlled trials comparing intra-articular sodium hyaluronate (IA-SH) injections is limited by a variety of methodological flaws. The evidence is consistent in suggesting that there is a small incremental benefit in IA-SH treatment over the benefit achieved with placebo-control treatments.

The two available studies comparing IA-SH treatment to pharmacologic treatment with non-steroidal anti-inflammatory drugs (NSAIDs) suggest IA-SH injections have comparable effectiveness to NSAIDs.

There is inadequate data to determine:

- the net effect of multiple courses of IA-SH treatment on health outcomes and
- the clinical efficacy of SH injections in joints other than the knee.

PRICING:

Hyalgan is supplied in 2 milliliter vials or prefilled syringes and requires refrigeration. A course of therapy consists of one - 2 milliliter injection given once a week for five weeks, totaling five injections for one knee, known as a single treatment cycle.

Synvisc is supplied in 2 milliliter prefilled syringes. Synvisc can be stored at room temperature. A course of therapy consists of one - 2 milliliter injection given once a week for three weeks, totaling three injections for one knee, known as a single treatment cycle.

Supartz is supplied in 2.5 milliliter prefilled syringes. Supartz can be stored at room temperature. A course of therapy consists of one - 2.5 milliliter injection given once a week for five weeks, totaling five injections for one knee, known as a single treatment cycle.

There may be a separate charge for aspiration and/or injection of the knee joint(s). The initial office visit to initiate hyaluronan therapy may be billed using an evaluation and management (E&M) code. However, the use of both aspiration and/or injection code and an E&M code during subsequent visits for the sole purpose of the SA injections is not warranted.

Subcutaneous local anesthesia may be required to perform the intra-articular injection, but no additional allowance will be made for it.
One or both knees may require the therapy.

REFERENCES:


DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.