

HYALURONATE COMPOUNDING POWDER

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Hyaluronic acid is a naturally occurring polysaccharide belonging to the glycosaminoglycan family containing repeating disaccharide units of sodium-glucuronate-N-acetylglucosamine. It is widely distributed in body tissues and intracellular fluids and is secreted by specific cells of the synovial membrane (1).

Regulatory Status

FDA-approved indications:

1. Intradermal injection for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds (2)
2. Dressing and management of partial to full thickness dermal ulcers, wounds, irritations of the skin and first and second degree burns (3)

The following dosage forms are commercially available:

- Solution for intradermal injection
- Topical cream
- Topical gel
- Topical lotion
- Topical spray

Compounded injections for ocular use are not recommended by the FDA due to instabilities and commercially available products are recommended for ocular use. Injections for intradermal use are considered as being used for cosmetic purposes and are excluded from coverage. Topical preparations of hyaluronate if being used for cosmetic purposes, such as wrinkles or as a moisturizer, are also excluded from coverage.

Summary

In healthy synovial joints, hyaluronic acid maintains viscosity of the synovial fluid and supports the lubricating and shock-absorbing properties of the articular cartilage. In the eye, hyaluronic acid is naturally found in the extracellular matrix of vitreous and aqueous humor and protects corneal endothelial cells and other ocular structures (1-3).



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Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of hyaluronate powder while maintaining optimal therapeutic outcomes.

References

1. Clinical Pharmacology Web site. Hyaluronic Acid. Accessed on May 2, 2024.
2. Restylane [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; March 2022.
3. Bionect [package insert]. Charleston, SC: EPI Health, LLC; November 2017.