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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Neuromuscular Drugs	**Original Policy Date:**	April 8, 2016
Subject:	Hyaluronate Powder	**Page:**	1 of 4

Last Review Date: March 12, 2021

Hyaluronate Powder

Description

Hyaluronate Powder

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.

Related policies
Hyaluronic Acid Derivatives

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Hyaluronate powder may be considered **medically necessary** if it is for a FDA-approved indication supporting the use of the compounded ingredient for the diagnosis provided and if the conditions indicated below are met.

Hyaluronate powder is considered **investigational** in diagnoses that are off-label or in formulations that do not have a confirmed FDA approval of use.

Prior-Approval Requirements

Diagnoses

Patient must have the following:

FDA-approved indication supporting the use of the compounded ingredient for the diagnosis provided

AND ALL of the following:

1. The requested dosage form is for topical use
2. The requested dose/ strength does **NOT** exceed the maximum FDA-approved dose/strength for the requested ingredient
3. The requested strength is **NOT** commercially available
4. The powder is **NOT** being compounded into a formulation for ophthalmic use
5. The powder is **NOT** being compounded into a formulation for cosmetic use such as for wrinkles or as a moisturizer

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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).

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 February 3, 2021.
2. Restylane [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; May 2020.
3. Bionect [package insert]. Charleston, SC: EPI Health, LLC; November 2017.

Policy History

Date	Action
April 2016	New Addition to PA

March 2016	Annual editorial review Addition of the powder is not being compounded into a formulation for ophthalmic use per SME
June 2016	Annual review
September 2017	Annual editorial review and reference update
September 2018	Annual review and reference update
September 2019	Annual review
March 2020	Annual review and reference update
March 2021	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.