

Policy: MBP 80.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Xiaflex (collagenase clostridium histolyticum)

I. Policy:

Xiaflex (collagenase clostridium histolyticum)

II. Purpose/Objective:

To provide a policy of coverage regarding Xiaflex (collagenase clostridium histolyticum)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:

Xiaflex (collagenase clostridium histolyticum) is a combination of bacterial collagenases isolated and purified from the fermentation of *C. histolyticum* bacteria; collagenase lyses collagen, leading to enzymatic disruption of contracted Dupuytren cord or Peyronie plaque (both comprised primarily of collagen).

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Xiaflex (collagenase clostridium histolyticum) will be considered medically necessary when all of the following criteria are met:

1. For treatment of Dupuytren contracture:

- Medical record documentation of Dupuytren's contracture with a palpable cord AND
- Prescribed by a provider experienced in injection procedures of the hand and treating Dupuytren's contracture

LIMITATIONS:

Xiaflex® will be limited to a maximum of three (3) injections per cord

2. For treatment of Peyronie disease:

- Medical record documentation of a diagnosis of moderate to severe Peyronie's Disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy

LIMITATIONS:

Xiaflex will be limited to a maximum of 8 total injection procedures (4 treatment cycles) per plaque.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/8/10

Revised: 5/20/2014 (added criteria for Peyronie's disease), 9/21/21 (removal of pentoxifylline)

Reviewed: 10/11; 1/14, 1/20/2015, 11/6/2015, 10/26/16, 9/29/17, 8/30/18, 8/29/19, 8/26/20, 8/19/21