FDA INDICATIONS AND USAGE

Xiaflex® is indicated for the treatment of adult patients with Dupuytren’s Contracture (DC) with a palpable cord and for the treatment of adult men with Peyronie’s Disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

APPROVAL CRITERIA

For Dupuytren’s Contracture:
1. Patient is 18 years of age or older AND;
2. Patient has a confirmed diagnosis of Dupuytren’s Contracture with a palpable cord AND;
3. Prescribe by or in consultation with a healthcare provider experienced in injection procedures of the hand and in the treatment of DC AND;
4. Patient has not received surgical treatment (e.g., fasciotomy) on the selected primary joint within the last 90 days AND;
5. If two injections (two vials) are requested, they are for one of the following (a or b):
   a. One cord affecting two joints in the same finger OR;
   b. Two cords affecting two joints in the same hand AND;
6. Documentation that the flexion deformity is causing functional limitations.

For Peyronie’s Disease:
1. Patient is 18 years of age or older AND;
2. Patient has a confirmed diagnosis of Peyronie’s Disease (PD) with a palpable plaque and curvature deformity of at least 30 degrees and less than 90 degrees at the start of therapy AND;
3. Prescribed by or in consultation with a healthcare provider experienced in the treatment of male urological diseases AND;
4. Documentation that the patient has had stable disease defined by symptoms (I.E. penile curvature and pain) for at least 6 months AND;
5. Xiaflex is not being used for sexual or erectile dysfunction associated with Peyronie’s Disease (7AAC 105.110) AND;
6. Must be used in conjunction with penile modeling.

DENIAL CRITERIA
1. Failure to meet approval criteria.
CAUTIONS¹

- Tendon rupture or serious injury to the injected finger/hand may occur.
- Corporal rupture (penile fracture) or other serious injury to the penis may occur.
- Xiaflex® is contraindicated for Peyronie’s plaques that involve the penile urethra.
- Use caution in patients with abnormal anticoagulation.

DURATION OF APPROVAL

- Initial Approval: One treatment cycle
- Re-approval: One treatment cycle

(Administration no sooner than 4 week interval for Dupuytren’s Contracture (up to 3 cycles in total) and no sooner than 6 week interval and has greater than 15 degree deformity for Peyronie's Disease (up to 4 cycles in total))

QUANTITY LIMITS

- 2 vials (injections) per treatment cycle

REFERENCES / FOOTNOTES: