Xiaflex® (Collagenase Clostridium Histolyticum)

Policy Number: IEXD0226.01
Effective Date: January 1, 2021

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Applicable States

This Medical Benefit Drug Policy only applies to the states of Arizona, Maryland, North Carolina, Oklahoma, Tennessee, Virginia, and Washington.

Coverage Rationale

Xiaflex is proven and medically necessary for the treatment of:

- Dupuytren’s contracture when all of the following criteria are met:
  - For initial therapy all of the following:
    - Patient has diagnosis of Dupuytren’s contracture with a palpable cord; and
    - Patient is 18 years of age or older; and
    - Xiaflex is prescribed and administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren’s contracture; and
    - Documented contracture of at least 40 degrees flexion for a metacarpophalangeal (MP) joint contracture or at least 20 degrees flexion for a proximal interphalangeal (PIP) joint contracture; and
    - Documentation that the flexion deformity results in functional limitations; and
    - Patient has not received surgical treatment on the selected primary joint within the last 90 days; and
    - If two injections (two vials) are requested, they are for one of the following:
      - One cord affecting two joints in the same finger; or
      - Two cords affecting two joints in the same hand
  and
  - Xiaflex dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 0.58 mg per injection into a palpable cord; and
  - The total number of injections does not exceed 3 injections per cord at approximately 4-week intervals; and
  - Authorization is for no more than 2 injections in the same hand
  - For continuation of therapy, all of the following:
    - Patient has previously received Xiaflex; and

Related Policies

None
• Documentation of positive clinical response to Xiaflex; and
• Treatment request is for at least one of the following:
  – Metacarpophalangeal (MP) or proximal interphalangeal (PIP) contracture remains in affected cord since previous injection and the contracture is > 5 degrees
  – A different MP or PIP contracture will be injected

and
• If two injections (two vials) are requested, use is for one of the following:
  – One cord affecting two joints in the same finger; or
  – Two cords affecting two joints in the same hand

and
• Member has not received surgical treatment (e.g., fasciectomy, fasciotomy) on the selected primary joint within the last 90 days; and
• The previous treatment was at least 4 weeks ago; and
• Xiaflex dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 0.58 mg per injection into a palpable cord; and
• The total number of injections does not exceed 3 injections per cord at approximately 4-week intervals; and
• Authorization is for no more than 2 injections in the same hand

• Peyronie’s disease when all of the following criteria are met:
  o For initial therapy all of the following:
    ▪ Patient has diagnosis of Peyronie’s disease with both of the following:
      – Palpable plaque; and
      – Curvature deformity of greater than or equal to 30 degrees at the start of therapy
    and
    ▪ Patient is 18 years of age or older; and
    ▪ Xiaflex is prescribed and administered by a healthcare provider experienced in the treatment of male urological diseases; and
    ▪ Xiaflex dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 0.58 mg per injection into a Peyronie’s plaque; and
    ▪ Authorization is for no more than 2 injections
  o For continuation of therapy, all of the following:
    ▪ Patient has previously received Xiaflex; and
    ▪ Documentation of positive clinical response to Xiaflex; and
    ▪ Last treatment was at least 6 weeks ago; and
    ▪ Documented curvature deformity of ≥ 15 degrees remaining since last treatment cycle; and
    ▪ Patient has received less than 4 treatment cycles (i.e. less than 8 injections [2 injections per cycle]); and
    ▪ Xiaflex dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: 0.58 mg per injection into a Peyronie’s plaque; and
    ▪ Authorization is for no more than 2 injections

Xiaflex is considered unproven and not medically necessary for any other uses.

**Applicable Codes**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>20527</td>
<td>Injection, enzyme (e.g., collagenase), palmar fascial cord (i.e., Dupuytren's contracture)</td>
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<tr>
<td>26341</td>
<td>Manipulation, palmar fascial cord (i.e., Dupuytren's cord), post enzyme injection (e.g., collagenase), single cord</td>
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Background

Dupuytren's contracture is a relatively common disorder characterized by progressive fibrosis of the palmar fascia. It is a benign, slowly progressive fibroproliferative disease of the palmar fascia. Initial fascial thickening is usually seen as a nodule in the palm, which can be painful or painless and often goes unnoticed and undiagnosed. Joint stiffness and a loss of full extension develop insidiously over a variable period of time but typically decades. As the process evolves, nodules may progress over years to form longitudinal bands referred to as cords on the palmar fascia, and the finger gradually loses extension, with contractures that draw one or more fingers into flexion at the metacarpophalangeal (MCP) joint, proximal interphalangeal (PIP) joint, or both. The term Dupuytren disease (DD) is also used for this disorder, as the fingers are not always held in a fixed flexion deformity. The cause of Dupuytren's contracture is unknown; important factors include genetics, ethnicity, sex, and age and may include certain environmental factors and other diseases. The disorder, which most affects those of northern European ancestry, appears to have a pronounced genetic predisposition; 68 percent of male relatives of affected patients develop the disease. In a study involving patients from the Netherlands, Germany, and the United Kingdom, six of nine genetic loci found associated with genetic susceptibility to Dupuytren's disease contained genes encoding proteins in the Wnt-signaling pathway. Overstimulation of this pathway, which can regulate cellular proliferation, could potentially lead to fibroblast proliferation and nodule formation in this disorder through effects upon beta-catenin. Pathologically, Dupuytren's contracture is characterized by fibroblastic proliferation and disorderly collagen deposition with fascial thickening. Formation of a nodule or nodules occurs in the early proliferative stage of the disease and is the pathognomonic lesion of Dupuytren's contracture. Nodules form due to proliferation of fibroblasts in the superficial palmar fascia and histologically are composed of fibroblasts and type III collagen. Smooth muscle fibroblasts and myofibroblasts are present in the nodules; increased concentrations of prostaglandins are also found within the nodules and may influence myofibroblast contractility. The flexor tendons are not intrinsically involved, but invasion of the dermis occurs and results in characteristic puckering and tethering of the skin. The presence of CD3-positive lymphocytes and the expression of major histocompatibility complex (MHC) class II proteins also suggest a possible role for a T-cell mediated autoimmune response in this disorder.2

Peyronie’s disease is an acquired penile abnormality caused by fibrosis of the tunica albuginea, which may lead to pain, deformity, erectile dysfunction, and/or distress. It is thought that repeated minor trauma to the penis initiates a cascade involving extravascular protein deposition, fibrin trapping, and overexpression of cytokines, leading to collagen changes characteristic of the condition. Males around 50 years of age are most commonly affected. Peyronie’s disease has a variable course; for most patients, pain will resolve over time without intervention, but curvature deformities are less likely to resolve without treatment. Intrallesional therapy with Xiaflex may be used to treat curvature associated with Peyronie’s disease and is supported by American Urological Association guidelines.3

Clinical Evidence

Reference the Clinical Studies information provided in the product labeling.1

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Xiaflex is a combination of bacterial collagenases indicated for:

- The treatment of adult patients with Dupuytren’s contracture with a palpable cord
- The treatment of adult men with Peyronie’s disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy
Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for XIAFLEX® (collagenase clostridium histolyticum). Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist.

In general, Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Refer to the Medicare Benefit Policy Manual, Chapter 15, §50 - Drugs and Biologicals. (Accessed July 9, 2020)

References


Policy History/Revision Information

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<td>01/01/2021</td>
<td>• New Medical Benefit Drug Policy</td>
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Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.