Draft remit/appraisal objective
To appraise the clinical and cost effectiveness of collagenase clostridium histolyticum and potassium para-aminobenzoate within their marketing authorisations for treating Peyronie’s disease.

Background
Peyronie’s disease is a condition in which people develop plaques of fibrous, scar-like tissue in their penis, causing it to become overly curved. Epidemiological data on Peyronie’s disease are limited. Published prevalence rates range from 0.4 to 9%, with the highest prevalence in people with erectile dysfunction from causes other than Peyronie’s disease and in people with diabetes.¹ The average age of people with Peyronie’s disease is between 55 and 60 years.

Symptoms of Peyronie’s disease include penile pain, erectile dysfunction, penile deformity and difficulties during sexual intercourse, all of which can cause high levels of distress. Approximately 48% of people with Peyronie’s disease report mild or moderate depression requiring medical evaluation.²

Spontaneous improvement can occur; therefore clinical experts suggest waiting before recommending surgical correction. During the ‘waiting period’ people may be offered non-surgical treatments. The aim of these treatments is to improve symptoms and stabilise disease progression. There are no standard non-surgical treatment options for Peyronie’s disease. Options include pharmacological treatments, traction and vacuum devices, iontophoresis (the introduction of ionic medicinal compounds into the body through the skin by applying a local electric current to the affected area) and extracorporeal shockwave therapy (ESWT), which involves targeting sound waves at the plaque, generally using an ultrasound scanner. NICE Interventional procedure guidance 29 advises that, although ESWT is considered safe, there is inadequate evidence to show that it is effective. In severe cases which have not resolved after the suggested ‘waiting period’, it is possible to treat Peyronie’s disease with surgery. Surgery has been proven to be an effective treatment for treating Peyronie’s disease.
The technology
Collagenase clostridium histolyticum (Xiapex, Swedish Orphan Biovitrum AB) is a mixture of 2 purified collagenase enzymes isolated from the bacterium Clostridium histolyticum. Collagenase clostridium histolyticum has a marketing authorisation in the UK for 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. Collagenase clostridium is administered by injection.

Potassium para-aminobenzoate (Potaba, Glenwood GmbH) has a marketing authorisation in the UK for Peyronie's disease. Potassium para-aminobenzoate is administered orally.

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<tr>
<th>Interventions</th>
<th>Collagenase clostridium histolyticum</th>
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<tr>
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<td>Potassium para-aminobenzoate</td>
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<tr>
<td>Population(s)</td>
<td>Adults with Peyronie’s disease</td>
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<td>Comparators</td>
<td>• No treatment</td>
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<td></td>
<td>• Non-surgical treatment (including but not limited to pharmacological interventions and medical devices)</td>
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<td>• Surgical treatment</td>
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<td>Outcomes</td>
<td>The outcome measures to be considered include:</td>
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<td>• improvement in penile curvature from baseline</td>
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<td>• erectile function</td>
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<td>• depression</td>
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<td>• adverse effects of treatment</td>
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<td>• health-related quality of life</td>
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<td>Economic analysis</td>
<td>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</td>
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<td>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</td>
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<td>Costs will be considered from an NHS and Personal Social Services perspective.</td>
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Other considerations
Guidance will only be issued in accordance with the marketing authorisation.
If evidence allows, subgroups by degree of penile curvature at baseline will be considered.

Related NICE recommendations and NICE Pathways
Appraisals in development
‘Collagenase clostridium histolyticum for treating Dupuytren's contracture’ [ID621] Publication expected April 2015
Related Interventionsal Procedures:
‘Extracorporeal shockwave therapy for Peyronie's disease’ (2003) NICE interventional procedures guidance 29

Related National Policy
NHS England, Manual for Prescribed Specialised Services 2013/14

Questions for consultation
Is potassium para-aminobenzoate used for treating Peyronie’s disease in clinical practice?

Have all relevant comparators for collagenase clostridium histolyticum and potassium para-aminobenzoate been included in the scope? Which treatments are considered to be established clinical practice in the NHS for Peyronie’s disease? In particular:

- Should surgical treatments be included as comparator? Or would collagenase clostridium histolyticum be used before surgery?

How many months do clinicians in England recommend waiting before surgical intervention is considered appropriate for patients with Peyronie’s disease? Is immediate surgery indicated for a subgroup of people with Peyronie’s disease?

How is disease severity defined? How is disease severity factored into the decision as to whether to treat surgically?

Have all the relevant outcomes been included in the scope?

Is the subgroup suggested in ‘other considerations’ appropriate? Are there any other subgroups of people in whom collagenase clostridium histolyticum and potassium para-aminobenzoate are expected to be more clinically effective and cost effective or other groups that should be examined separately?
NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which collagenase clostridium histolyticum and potassium para-aminobenzoate are licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider collagenase clostridium histolyticum or potassium para-aminobenzoate to be innovative in their potential to make a significant and substantial impact on health-related benefits and how they might improve the way that current need is met (is this a ‘step-change’ in the management of Peyronie’s disease)?

Do you consider that the use of collagenase clostridium histolyticum or potassium para-aminobenzoate can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Multiple Technology Appraisal (MTA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute’s Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction)

References