

1.	<p><b>Treatment &amp; Condition</b></p> <p>Collagenase clostridium histolyticum for treating Dupuytren's contracture</p>
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA459 (July 2017)</p> <p>People who meet the inclusion criteria for the ongoing clinical trial (HTA-15/102/04), comparing collagenase clostridium histolyticum (CCH) with limited fasciectomy, are encouraged to participate in the study.</p> <p>For people not taking part in the ongoing clinical trial, CCH is recommended as an option for treating Dupuytren's contracture with a palpable cord in adults only if all of the following apply:</p> <ul style="list-style-type: none"> <li>• There is evidence of moderate disease (functional problems and metacarpophalangeal joint contracture of 30° to 60° and proximal interphalangeal joint contracture of less than 30° or first web contracture) plus up to 2 affected joints.</li> <li>• Percutaneous needle fasciotomy (PNF) is not considered appropriate, but limited fasciectomy is considered appropriate by the treating hand surgeon.</li> <li>• The choice of treatment (CCH or limited fasciectomy) is made on an individual basis after discussion between the responsible hand surgeon and the patient about the risks and benefits of the treatments available.</li> <li>• One injection is given per treatment session by a hand surgeon in an outpatient setting.</li> </ul>
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b></p> <p>Uncertain as NICE has not provided a costing template. The number of people in Northern Ireland expected to take up TA459 will be monitored through the cost per case mechanism.</p>
4.	<p><b>Patient Access Scheme Availability</b></p> <p>(Yes/<u>No</u>)</p> <p>No requirement for a Patient Access Scheme</p>
5.	<p><b>Costs</b> (<i>before PAS if applicable</i>)</p>
5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>The recommended dose of CCH is 0.58mg per injection into a palpable Dupuytren's cord. The volume of solvent needed and the volume of reconstituted CCH to be administered into the cord differs depending on the type of joint being treated.</p> <ul style="list-style-type: none"> <li>• For cords affecting metacarpophalangeal joints, each dose is administered</li> </ul>

	<p>in an injection volume of 0.25ml.</p> <ul style="list-style-type: none"> <li>For cords affecting proximal interphalangeal joints, each dose is administered in an injection volume of 0.20ml.</li> </ul> <p>Injections in up to 2 cords or 2 affected joints in the same hand can be given during a treatment visit. Two palpable cords affecting 2 joints may be injected or 1 palpable cord affecting 2 joints in the same finger may be injected at 2 locations during a treatment visit. Each injection contains a 0.58mg dose. If the disease has resulted in multiple contractures, additional cords may be treated at other treatment visits approximately 4 weeks apart.</p> <p>The Summary of Product Characteristics for CCH (Xiapex<sup>®</sup>) indicates that clinical study experience with Xiapex<sup>®</sup> is currently limited to up to 3 injections per cord and up to 8 injections in total.</p> <p>The cost of CCH is £650 per 0.9mg vial [BNF 72]</p> <p>Hence at the maximum dose of 8 injections in total, the <u>maximum</u> cost per patient per course would be 8 x £650 = £5,200</p>
5.2	<p><b>Infrastructure costs Per annum</b></p> <p>Any additional infrastructure costs associated with the introduction of this treatment will be dealt with as part of the routine commissioning process.</p>
6.	<p><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p><b>Commissioning arrangements</b></p> <p>This regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis for a period of 12 months. After this time, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.</p>
8.	<p><b>Monitoring arrangements</b></p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications.</p>
9.	<p><b>DoH (NI) Legislative/Policy Caveats</b></p> <p>This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.</p>