

1.	<p><b>Treatment &amp; Condition</b></p> <p>Holoclar for treating limbal stem cell deficiency after eye burns.</p>
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA467 (August 2017)</p> <p>Holoclar (ex vivo expanded autologous human corneal epithelial cells containing stem cells) is recommended as an option in people with moderate to severe limbal stem cell deficiency after eye burns, only if:</p> <ul style="list-style-type: none"> <li>• It is used to treat 1 eye <b>and</b>;</li> <li>• People have already had a conjunctival limbal autograft <b>or</b>;</li> <li>• There is not enough tissue for a conjunctival limbal autograft or it is contraindicated <b>and</b>;</li> <li>• The company provides it with the discount agreed in the patient access scheme.</li> </ul> <p>Moderate to severe limbal cell deficiency is defined by the presence of superficial corneal neovascularisation in at least 2 corneal quadrants, with central corneal involvement, and severely impaired visual acuity.</p> <p>Holoclar is recommended in people with moderate to severe limbal stem cell deficiency after eye burns for treating both eyes only:</p> <ul style="list-style-type: none"> <li>• In the context of research and;</li> <li>• When there is not enough tissue for a conjunctival limbal autograft.</li> </ul> <p>Such research should be designed to generate robust evidence of the clinical- and cost-effectiveness of Holoclar in treating 2 eyes in people who do not have enough tissue for a conjunctival limbal graft.</p>
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b></p> <p>The NICE resource impact statement indicates that the guidance is not expected to have a significant impact on resources. This is because the prevalent population is small. Based on a pro rata calculation from the estimates for England given in the NICE Resource Impact Statement, the population treated with Holoclar is estimated to be around 3 for Northern Ireland.</p> <p>Local clinical advice indicates that around 2-5 patients will be treated with this therapy.</p>
4.	<p><b>Patient Access Scheme Availability</b></p> <p><b>(Yes/No)</b></p> <p>The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of Holoclar, with the</p>

	discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.
<b>5.</b>	<b>Costs</b>
<b>5.1</b>	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>A single treatment for one eye costs £80,000 excluding VAT.</p> <p>Exact dosage depends on the size of the corneal surface: the recommended dose is 79,000 to 316,000 cells/cm<sup>2</sup>.</p>
<b>5.2</b>	<p><b>Infrastructure costs Per annum</b></p> <p>The implementation of NICE TA467 is unlikely to result in significant change in infrastructure requirements. The HSC Board will work with the Belfast Trust to agree arrangements for patients to access this service from UK centres.</p> <p>The harvested population of corneal stem cells will need to be transported to the company's lab for expansion and then transported back for implantation into the eye. The service will be available from a limited number of centres in the UK.</p>
<b>6.</b>	<p><b>Expected implementation period</b></p> <p>There is no impediment to implementation of this guidance.</p>
<b>7.</b>	<p><b>Commissioning arrangements</b></p> <p>This treatment will be formally commissioned by the HSCB on a cost per case basis.</p>
<b>8.</b>	<p><b>Monitoring arrangements</b></p> <p>The HSC Board will monitor information on this regime through cost per case requests.</p>
<b>9.</b>	<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>