

1	<p>Treatment & Condition</p> <p>Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for treating recurrent ovarian cancer</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal Guidance (TA389) April 2016</p> <ul style="list-style-type: none"> • Paclitaxel in combination with platinum or as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer. • Pegylated liposomal doxorubicin hydrochloride (PLDH) as monotherapy is recommended within its marketing authorisation as an option for treating recurrent ovarian cancer. • PLDH in combination with platinum is recommended as an option for treating recurrent ovarian cancer^{1,2} • The following are not recommended within their marketing authorisations for treating the first recurrence of platinum-sensitive ovarian cancer: <ul style="list-style-type: none"> - gemcitabine in combination with carboplatin - trabectedin in combination with PLDH - topotecan. <p>The appraisal committee was unable to make recommendations on the use of these technologies for treating platinum-sensitive ovarian cancer beyond the first recurrence.</p> <ul style="list-style-type: none"> • Topotecan is not recommended within its marketing authorisation for treating recurrent platinum-resistant or platinum-refractory ovarian cancer. <p>This guidance (TA389) is a review of NICE technology appraisal TA91 (May 2005) and TA 222 (April 2011) paclitaxel, pegylated liposomal doxorubicin hydrochloride and topotecan for second-line or subsequent treatment of advanced ovarian cancer in which paclitaxel, PLDH and topotecan were recommended as options for recurrent ovarian cancer.</p> <ol style="list-style-type: none"> 1. At the time of writing, PLDH in combination with platinum did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Good practice in prescribing medicines – guidance for doctors for further information. 2. The use of PLDH (Caelyx[®]) in combination with platinum is outside the terms of the marketing authorisation for Caelyx[®]. Consequently the statutory funding requirement does not apply to this recommendation.

3	<p>Number of people in Northern Ireland expected to take up service/therapy <i>(including new cases per year)</i></p> <p>TA389 is a review of previous NICE TA 91.. This guidance relates to a small cohort of patients and these regimens are currently routinely commissioned for this indication. It is therefore expected that there is no service or resource impact with implementation of TA 389.</p>
4	<p>Patient Access Scheme availability</p> <p>Not applicable</p>
5	<p>Costs <i>(before PAS if applicable)</i></p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p><u><i>Paclitaxel</i></u> Paclitaxel is administered by intravenous infusion. The recommended dosage is 175mg/m² of body surface area administered over a period of 3 hours, with a 3-week interval between treatment cycles.</p> <p>At list price, the cost of a dose of paclitaxel 175 mg/m² (based on an average body surface area of 1.7m²) is £601 per 3-weekly cycle (excluding administration costs).</p> <p><u><i>Pegylated liposomal doxorubicin hydrochloride (PLDH)</i></u> PLDH is administered by intravenous infusion. The recommended dosage is 50mg/m² of body surface area once every 4 weeks for as long as the disease does not progress and the patient continues to tolerate treatment.</p> <p>The cost per dose of PLDH 50mg/m² (based on an average body surface area of 1.7m²) on day 1 of every 28-day cycle is £1,425 (excluding administration costs).</p>
5.2	<p>Infrastructure costs per patient per annum</p> <p>Any additional infrastructure costs associated with the introduction of new cancer therapies will be managed as part of the routine commissioning process.</p>
5.3	<p>Current in year costs</p> <p>Paclitaxel and PLDH are currently both in use and topotecan is not used. It is unlikely that the guidance will result in a significant change in the resource required as clinical practice is not expected to change substantially.</p>
5.4	<p>Recurrent overall costs per annum <i>(including additional costs)</i></p> <p>This guidance (TA389) is a review of NICE technology appraisal TA91 (May 2005) paclitaxel, pegylated liposomal doxorubicin hydrochloride and topotecan for second-line or subsequent treatment of advanced ovarian cancer in which paclitaxel, PLDH and topotecan were recommended as options for recurrent ovarian cancer.</p> <p>Expert clinical opinion suggests that paclitaxel and PLDH are currently both in use and topotecan is not used. It is unlikely that the guidance will result in a significant</p>

	change in resource use in the NHS because it is considered that clinical practice will not change substantially as a result of this guidance.
5.5	Opportunities for cost savings and how these will be secured There may be modest cost savings.
6	Expected implementation period There is no impediment to immediate implementation for new patients.
7	Commissioning arrangements Given the very small volume of patients expected to take up these therapies for this indication, any reduction in use is unlikely to have a significant impact on current commissioning arrangements.
8	Monitoring arrangements HSCB currently routinely reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other units.
9	DHSSPS Legislative/Policy Caveats 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.