Indication	As maintenance monotherapy treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who have a recent FIRST OR SUBSEQUENT relapse of platinum-sensitive disease who are now in response following a SECOND OR SUBSEQUENT platinum-based chemotherapy: a) who have a deleterious or suspected deleterious germline and/or somatic BRCA mutation b) who do NOT have a deleterious or suspected deleterious germline and/or somatic BRCA mutation NB No previous treatment with a PARP inhibitor, unless an NHSE commissioned PARP inhibitor has had to be stopped within 3 months of starting, solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. **or** As maintenance monotherapy treatment in patients with high grade stage III or IV epithelial ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy and who DO NOT have a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation but do have a **POSITIVE** status for homologous recombination deficiency. NB the patient has not previously received any PARP inhibitor unless the patient has received rucaparib as part of a company early access scheme for this 1st line maintenance therapy or have had 1st line maintenance niraparib monotherapy that was stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. **or** As maintenance monotherapy treatment in patients with high grade epithelial stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in response following platinum-based FIRST line chemotherapy for a tumour which has a **NEGATIVE** status for a deleterious or suspected deleterious BRCA germline and/or somatic BRCA mutation AND a **NEGATIVE** or **UNKNOWN** status for homologous recombination deficiency and are not suitable for maintenance bevacizumab or previously received bevacizumab monotherapy as 1st line maintenance therapy and this has had to be stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression NB the patient has not previously received any PARP inhibitor unless the patient has received rucaparib as part of a company early access scheme for this 1st line maintenance indication or have had 1st line maintenance niraparib monotherapy that was stopped within 3 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. In all indications' treatment should start within 8 weeks of completing a minimum of 4 cycles of platinum-containing chemotherapy from the date of the last infusion. A formal medical review as to whether maintenance treatment with rucaparib should continue or not will be scheduled to occur at least by the start of the third cycle of treatment.
Treatment Intent	Palliative.
Frequency and number of cycles	Repeat every 28 days. In maintenance monotherapy treatment in patients who are now in response following a SECOND OR SUBSEQUENT platinum-based chemotherapy (see full indication above) continue until disease progression, unacceptable toxicity or patient's choice to stop treatment.

	In maintenance monotherapy treatment in patients who are now in response following platinum-based FIRST line chemotherapy (see full indication above) continue until disease progression, unacceptable toxicity or patient's choice to stop treatment or completion of 2 years, whichever is the soonest.
Monitoring Parameters pre-treatment	• **Virology screening:** All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion. • FBC, U&E's and LFTs baseline and prior to each cycle. • Withhold if neutrophils <1.0 and/or platelets <75, and / or haemoglobin <80g/L, and monitor blood counts weekly until recovery, and consider dose reduction. • **Hepatic Impairment:** No dose adjustment required in mild or moderate impairment. Patients with moderate impairment should be closely monitored for changes in hepatic function and adverse reactions. Not recommended for use in severe hepatic impairment (Bilirubin >3x ULN). • **Renal Impairment:** • No dose adjustment is required in patients with mild or moderate (CrCl 31-50 ml/min) renal impairment. No data available in severe impairment (CrCl <30ml/min), therefore rucaparib is not recommended for use, clinical decision to use**.** • **Common drug interactions (for comprehensive list refer to BNF/SPC):** Caution when rucaparib is co-administered with medicines that are strong inhibitors of P-gp (clarithromycin, erythromycin, ritonavir and verapamil), or strong CYP3A4 inhibitors (e.g., ketoconazole, ritonavir, clarithromycin, itraconazole, voriconazole, posaconazole) or inducers (e.g., carbamazepine, phenytoin, rifampicin). Caution should be exercised and additional drug level monitoring / INR (as appropriate) when co-administered with medicinal products with a narrow therapeutic index metabolised by CYP1A2 (e.g. tizanidine, theophylline) and CYP2C9 (e.g. warfarin, phenytoin). Caution when co-administering medicinal products that are CYP3A substrates with a narrow therapeutic index (e.g., alfentanil, astemizole, cisapride, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus, terfenadine). Caution is advised when metformin is co-administered with rucaparib. • **Dose Modification:** Moderate to severe (grade 3-4) haematological and non-haematological adverse reactions may require dose reduction. First dose reduction, 500 mg twice daily. Second dose reduction, 400 mg twice daily. Third dose reduction, 300 mg twice daily. • **Management of treatment emergent AST/ALT elevation:** Grade 3 (>5-20 x ULN) without other signs of liver dysfunction; Monitor LFTs weekly until resolution to </= 5 x ULN. Continue rucaparib provided bilirubin is < ULN and alkaline phosphatase is < 3 x ULN. Interrupt treatment if AST/ALT levels do not decline within 2 weeks until </= 5 x ULN, then resume rucaparib at the same or at a reduced dose. Grade 4 (>20 x ULN): Interrupt rucaparib until values return to </= 5 x ULN; then resume rucaparib with a dose reduction and monitor LFTs weekly for 3 weeks. • **AML/MDS:** Myelodysplastic syndrome/acute myeloid leukaemia (MDS/AML) has been reported in some patients receiving rucaparib. If haematological parameters have not recovered to CTCAE Grade 1 or better (ie neutrophils still <1.5 and/or platelets still <75) after 4 weeks, the patient should be referred to a haematologist for further investigations. If MDS/AML is confirmed treatment with rucaparib should be discontinued.

	• **Missed dose:** If a dose is missed, the patient should resume taking rucaparib with the next scheduled dose. If a patient vomits post dose they should not re take the dose and resume with the next scheduled dose. • **Driving:** Caution when driving or using machines is advised for patients who report fatigue, nausea, or dizziness during treatment. • **Photosensitivity:** Patients should be advised to avoid spending time in direct sunlight, and use appropriate protection with a hat, protective clothing and SPF 50 sunscreen when outdoors. • For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet and Macmillan information sheet.
References	SPC accessed online 10.07.24 KMCC protocol GYN-041 V1 CDF list V 1.314 and CDF list V1.318 accessed online 12.08.2024

NB For funding information, refer to CDF and NICE Drugs Funding List

Repeat every 28 days: To start within 8 weeks of completing a minimum of 4 cycles of platinum-containing chemotherapy

TTO	Drug	Dose	Route	Directions
Day 1	**RUCAPARIB**	**600mg**	PO	BD (12 hours apart) Can be taken with or without food. Available as 200mg, 250mg and 300mg tablets. Dispense 30 days' supply.
	Metoclopramide	10mg	PO	TDS PRN Do not take for more than 5 days continuously. (dispense 28 tablets on cycle 1, then only if specified)