RUCAPARIB (Rubraca)

INDICATION (ICD10) C56

Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/) (RUC1) (RUC2) (RUC3) (RUC4)

1. Rucaparib monotherapy as maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who have a deleterious or suspected deleterious germline and/or somatic BRCA1 or BRCA2 mutation and who have a recent FIRST OR SUBSEQUENT relapse of platinum-sensitive disease and who are now in partial or complete response following a SECOND OR SUBSEQUENT platinum-based chemotherapy (minimum 4 cycles of which last dose administered less than 8 weeks ago) and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level. PS 0 or 1. (TA1007)
2. Rucaparib monotherapy as maintenance treatment in patients with high grade epithelial ovarian, fallopian tube or primary peritoneal carcinoma who do NOT have a deleterious or suspected deleterious germline and/or somatic BRCA mutation and who have a recent FIRST OR SUBSEQUENT relapse of platinum-sensitive disease and who are now in partial or complete response following a SECOND OR SUBSEQUENT line platinum-based chemotherapy (minimum 4 cycles of which last dose administered less than 8 weeks ago) and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level. PS 0 or 1. (TA1007)
3. Rucaparib monotherapy as maintenance treatment in patients with high grade epithelial FIGO stage III or IV ovarian, fallopian tube or primary peritoneal carcinoma who are in partial or complete response following completion of platinum-based FIRST line chemotherapy (minimum 4 cycles of which last dose administered less than 8 weeks ago) and there is no evidence of progressive disease on the post-treatment scan or a rising CA125 level 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 as defined by the presence of genomic instability. PS 0 or 1.
4. Rucaparib monotherapy as maintenance treatment in patients for whom bevacizumab maintenance is NOT a treatment option, 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 (minimum 4 cycles of which last dose administered less than 8 weeks ago) 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 as defined by the presence of genomic instability. PS 0 or 1.

REGIMEN

RUCAPARIB 600mg tablet orally twice daily

Maintenance rucaparib monotherapy to start within 8 weeks from the date of the first day of the last cycle of 1st line chemotherapy.

CYCLE FREQUENCY AND NUMBER OF CYCLES

Maintenance following 1st line platinum regimen (RUC3 or RUC4) - daily continuously up to maximum 2 calendar years from 1st rucaparib dose.
Maintenance following 2nd or subsequent line platinum regimens (RUC1 or RUC2) - daily continuously until progression or toxicity.
A formal medical review as to whether maintenance treatment with rucaparib for all indications should continue or not will be scheduled to occur at least by the start of the third 4 weekly cycle of treatment.

ADMINISTRATION
Available as 200mg, 250mg and 300mg tablets
Swallow whole with or without food.

ANTI-EMETICS
Minimal emetic risk all days

EXTRAVASATION AND TYPE OF LINE / FILTERS
Not applicable

INVESTIGATIONS
Blood results required before SACT administration
FBC, U&E and LFTs after 2 weeks, then minimum monthly for first 4 months then alternate months with stable disease
Neutrophils x 10^9/L ≥1.5
Platelets x 10^9/L ≥100

MAIN TOXICITES AND ADVERSE REACTIONS

Rucaparib	Diarrhoea Myelosuppression Nausea, vomiting Raised creatinine

INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS
(not exhaustive list check SPC/BNF/Stockleys)

Rucaparib	Concomitant use of strong or moderate CYP3A inhibitors is not recommended and alternative agents should be considered. If a strong CYP3A inhibitor must be co-administered, the recommended olaparib dose reduction is to 100mg twice daily. If a moderate CYP3A inhibitor must be co-administered, the recommended olaparib dose reduction is to 150mg twice daily.

DOSE MODIFICATIONS

Starting dose	600mg bd
First dose reduction	500mg bd
Second dose reduction	400mg bd
Third dose reduction	300mg bd

Hepatic impairment
Rucaparib
No initial dose adjustment is necessary for patient with mild hepatic impairment (bilirubin ≤ULN and AST >ULN, or bilirubin 1–1.5xULN and any AST) There are no data in patients with moderate to severe hepatic impairment.

Renal impairment
Rucaparib
No dose adjustment is necessary for patient with CrCl ≥30ml/min. There are no data in patients with CrCl <30ml/min, or patients on dialysis

REFERENCES
1. Coleman, R et al; Lancet 2017; 390 (10106): 1949–1961