TALAZOPARIB (Talzenna)

INDICATION (ICD10) C50

Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/) (TAL1)

1. Talazoparib monotherapy for treatment of adults with deleterious or suspected deleterious germline BRCA1 or 2 mutations who have HER-2 negative locally advanced or metastatic breast cancer previously treated with an anthracycline and/or taxane in the adjuvant/neoadjuvant/advanced disease settings and also treated with prior endocrine-based therapy if the patient has hormone-receptor positive disease. Not received any previous treatment with a PARP inhibitor or has received adjuvant olaparib and this was completed without disease progression during therapy or within 12 months of its completion. PS 0, 1 or 2.

REGIMEN

TALAZOPARIB 1mg orally once daily

CYCLE FREQUENCY AND NUMBER OF CYCLES

Continuously until disease progression. A formal medical review as to how talazoparib is being tolerated and whether talazoparib 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 0.25mg and 1mg capsules

ANTI-EMETICS

Minimal risk

CONCURRENT MEDICATION REQUIRED

Talazoparib	None required

EXTRAVASATION AND TYPE OF LINE / FILTERS

Not applicable

INVESTIGATIONS

Blood results required before SACT administration

FBC, U&E and LFTs every month

Haemoglobin g/dl ≥8 (see dose modifications for further details)

Neutrophils x 10^9/L ≥1.0 (see dose modifications for further details)

Platelets x 10^9/L ≥50 (see dose modifications for further details)

Baseline weight and every cycle

MAIN TOXICITES AND ADVERSE REACTIONS

Talazoparib	Myelosuppression Myelodysplastic syndrome / acute myeloid leukaemia

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

Talazoparib	Lots of interactions check carefully. Strong inhibitors of P-gp may lead to increased talazoparib exposure. Concomitant use of strong P-gp inhibitors during treatment with talazoparib should be avoided.

DOSE MODIFICATIONS

Talazoparib

First dose reduction	0.75mg
Second dose reduction	0.5mg
Third dose reduction	0.25mg

Haematological

Talazoparib

Haemoglobin <8g/dl	Withhold talazoparib until levels resolve to ≥9. Then resume talazoparib at next lower dose.
Platelet count <50x10^9/L	Withhold talazoparib until levels resolve to ≥75. Then resume talazoparib at next lower dose.
Neutrophils <1.0x10^9/L	Withhold talazoparib until levels resolve to ≥1.5. Then resume talazoparib at next lower dose.

Non-haematological

Talazoparib

Non-haematological adverse reaction grade 3 or grade 4, withhold until ≤grade 1. Consider resuming talazoparib at next lower dose or discontinue.

Hepatic impairment

Talazoparib

No dose adjustment is required for patients with mild hepatic impairment (total bilirubin ≤1×ULN and aspartate aminotransferase (AST) >ULN, or total bilirubin >1.0 to 1.5×ULN and any AST), moderate hepatic impairment (total bilirubin >1.5 to 3.0×ULN and any AST) or severe hepatic impairment (total bilirubin >3.0×ULN and any AST.

Renal impairment

Talazoparib

Mild renal impairment (CrCl 60-90mL/min)	No dose adjustment is required.
Moderate renal impairment (CrCl 30-59mL/min)	The recommended starting dose of talazoparib is 0.75mg once daily.
Severe renal impairment (CrCl 15-29mL/min)	The recommended starting dose of talazoparib is 0.5mg once daily.
CrCl <15mL/min or requiring haemodialysis	Talazoparib has not been studied.

REFERENCES

1. SPC
2. Blueteq criteria