fallopian tube or primary peritoneal cancer that has responded to the most recent course of platinum-based chemotherapy in adults, only if:

- they have a germline BRCA mutation and have had 2 courses of platinum-based chemotherapy, **or**
- they do not have a germline BRCA mutation and have had 2 or more courses of platinum-based chemotherapy, **and**
- the conditions in the managed access agreement for niraparib are followed.

Patients whose treatment was started within the NHS before this guidance was published should have the option to continue treatment, without change to their funding arrangements, until they and their NHS clinician consider it appropriate to stop.

www.nice.org.uk/guidance/ta528

Scottish Medicines Consortium (SMC) decisions

SMC No. 1341/18

The *Scottish Medicines Consortium* has advised (August 2018) that niraparib (*Zejula*®) is accepted for restricted use within NHS Scotland as monotherapy for the maintenance treatment of adults with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy. It is restricted to those patients who do not have a germline BRCA mutation. This advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland or a list price that is equivalent or lower.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug.

Capsule

CAUTIONARY AND ADVISORY LABELS 25

- **Zejula** (Tesaro UK Ltd) ▼
  Niraparib (as Niraparib tosylate monohydrate) 100 mg Zejula 100mg capsules | 56 capsule PoM £4,500.00 (Hospital only) | 84 capsule PoM £6,750.00 (Hospital only)

Olaparib

26-Feb-2020

- **DRUG ACTION** Olaparib is a PARP inhibitor. PARP are enzymes that repair damaged DNA in cancer cells and, in the absence of functional BRCA, inhibition of PARP results in an inability of cancer cells to repair. Therefore inhibition of PARP results in an antineoplastic effect.

- **INDICATIONS AND DOSE**

Ovarian cancer (initiated by a specialist) | Fallopian tube cancer (initiated by a specialist) | Peritoneal cancer (initiated by a specialist)

- BY MOUTH USING CAPSULES
- Adult: 400 mg twice daily, patients should start treatment no later than 8 weeks after completion of their final dose of the platinum-containing regimen, for dose adjustments due to side-effects—consult product literature
- BY MOUTH USING TABLETS
- Adult: 300 mg twice daily, patients should start treatment no later than 8 weeks after completion of their final dose of the platinum-containing regimen, for dose adjustments due to side-effects—consult product literature

DOSE ADJUSTMENTS DUE TO INTERACTIONS

- Manufacturer advises if concurrent use of moderate inhibitors of CYP3A4 is unavoidable, reduce dose of *capsules* to 200 mg twice daily and *tablets* to 150 mg twice daily.
- Manufacturer advises if concurrent use of potent inhibitors of CYP3A4 is unavoidable, reduce dose of *capsules* to 150 mg twice daily and *tablets* to 100 mg twice daily.

DOSE EQUIVALENCE AND CONVERSION

- Manufacturer advises capsules and tablets are not interchangeable on a milligram-for-milligram basis due to differences in dosing and bioavailability.

IMPORTANT SAFETY INFORMATION

RISKS OF INCORRECT DOSING OF ORAL ANTI-CANCER MEDICINES

See Cytotoxic drugs p. 938.

MHRA/CHM ADVICE: *LYNPARZA*® (OLAPARIB): RISK OF MEDICATION ERRORS WITH NEW PHARMACEUTICAL FORM (MAY 2018)

A tablet formulation of olaparib was approved by the European Commission in May 2018. Capsules and tablets are not to be substituted on a milligram-to-milligram basis due to differences in dosing and bioavailability of each formulation. Prescribers should specify the formulation and dosage of olaparib on each prescription and pharmacists should ensure that the correct formulation and dose is dispensed. Patients should be instructed on the correct dose they should take for their capsules or tablets and if switched, informed of the difference in dosing.

- **INTERACTIONS** → Appendix 1: olaparib
- **SIDE-EFFECTS**
  - **Common or very common** Agranulocytosis · anaemia · appetite decreased · asthenia · cough · decreased leucocytes · diarrhoea · dizziness · dyspnoea · erythropenia · gastrointestinal discomfort · headache · nausea · neutropenia · neutropenic infection · neutropenic sepsis · oral disorders · skin reactions · taste altered · thrombocytopenia · vomiting
  - **Frequency not known** Haematotoxicity · neoplasms · pneumonitis

SIDE-EFFECTS, FURTHER INFORMATION **Haematological toxicity** Withhold treatment if severe haematological toxicity develops; further analysis recommended if toxicity still present 4 weeks after treatment withdrawal.

Pneumonitis If dyspnoea, cough and fever, or radiological abnormalities develop, withhold treatment and investigate; if pneumonitis confirmed, discontinue.

- **CONCEPTION AND CONTRACEPTION** Manufacturer advises effective contraception during treatment and for 1 month after receiving the last dose. Consider an additional non-hormonal method of contraception.
- **PREGNANCY** Manufacturer advises avoid—toxicity in *animal* studies.
- **BREAST FEEDING** Manufacturer advises avoid during treatment and for 1 month after last dose—no information available.
- **HEPATIC IMPAIRMENT** Manufacturer advises avoid in severe impairment (no information available).
- **RENAL IMPAIRMENT** Manufacturer advises avoid in severe impairment unless benefit outweighs potential risk—no information available.

Dose adjustments For *capsules*, manufacturer advises reduce dose to 300 mg twice daily in moderate impairment.

For *tablets*, manufacturer advises reduce dose to 200 mg twice daily in moderate impairment.

- **MONITORING REQUIREMENTS** Manufacturer advises monitor full blood count before treatment initiation, then every month for the first 12 months of treatment and periodically thereafter.
- **DIRECTIONS FOR ADMINISTRATION** Manufacturer advises *capsules* should be taken at least 1 hour after food, and food should preferably be avoided for up to 2 hours after administration.