LYNPARZA is now PBS listed for both somatic BRCAm and germline BRCAm in 2nd-line maintenance of platinum-sensitive relapsed high-grade ovarian cancer (≥2 prior courses of platinum-based regimens).

### 2nd-LINE MAINTENANCE OF PLATINUM-SENSITIVE RELAPSED HIGH-GRADE OVARIAN CANCER¹

<table>
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<th>Somatic BRCAm</th>
<th>Germline BRCAm</th>
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<td><strong>BRCAm testing</strong></td>
<td><strong>NEW Aug 1st</strong> MBS Item 73301 (Tumour BRCA Testing)²*</td>
<td>*<em>MBS Item 73295²</em></td>
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<tr>
<td><strong>LYNPARZA access</strong></td>
<td><strong>NEW Aug 1st</strong> PBS listed (restrictions apply)³*</td>
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</tbody>
</table>

¹Restrictions apply, please refer to the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) Schedule for full criteria²,³
2nd-LINE MAINTENANCE OF PLATINUM-SENSITIVE RELAPSED, BRCAm, HIGH-GRADE EPITHELIAL OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER

**TGA indication**

- **Treatment:** maintenance monotherapy
- **Tumour type:** platinum-sensitive relapsed high-grade ovarian cancer, fallopian tube or primary peritoneal cancer
- **Histology:** high-grade epithelial cancer
- **Prior treatment:** ≥2 prior courses of platinum-based regimens
- **Response:** in response (CR or PR) after platinum-based chemotherapy

**LYNPARZA dosing**

2 tablets twice a day

- With or without food
- 300 mg twice daily (recommended starting dose)

**Tumour (somatic) and germline BRCAm testing**

- MBS Item 73301 – tumour BRCAm test
- MBS Item 73295 – germline test when tumour test not feasible

**PBS listed (authority required) for 2nd-line maintenance of somatic and germline BRCAm**

**Initial treatment**

LYNPARZA is PBS-reimbursed for the permitted 2nd-line maintenance TGA indication (see left) with additional restrictions:

- High-grade serous ovarian cancer, fallopian tube or primary peritoneal cancer
- Platinum sensitive (disease progression >6 months after completion of the penultimate platinum regimen)
- Class 4 or 5 BRCA1 or BRCA2 gene mutation

**Continuing treatment**

LYNPARZA is PBS-reimbursed for the permitted 2nd-line maintenance TGA indication (see left) with additional restrictions:

- High-grade serous ovarian cancer
- No disease progression while receiving treatment with this drug for this condition

**Grandfathering sBRCAm**

- When transferring patients from AstraZeneca Access to PBS access, commence patients using initial treatment criteria (above)
Before prescribing, please review full product information available on request from AstraZeneca on 1800 805 342 or www.astrazeneca.com.au/PI

Lynparza® (olaparib) Tablets Minimum Product Information. INDICATIONS: Ovarian cancer: *Monotherapy for the maintenance treatment of adult patients with advanced BRCA-mutated (germline or somatic) high-grade serous ovarian, fallopian tube or primary peritoneal cancer who are in response (complete response or partial response) to first-line platinum-based chemotherapy. BRCA mutation status should be determined by an experienced laboratory using a validated test method. Monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high-grade serous ovarian, fallopian tube or primary peritoneal cancer who are in response (complete response or partial response) after platinum-based chemotherapy. Prior treatment must have included at least 2 courses of platinum-based regimens. *Recur Cancer: *Monotherapy for the treatment of adult patients with germline BRCA-mutated HER2-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Germline BRCA mutation (gBRCA) status should be determined by an experienced laboratory using a validated test method. Dosing & Administration: Important Administration Information Lynparza is also available as a 50 mg capsule. DO NOT substitute Lynparza tablets (100 mg and 150 mg) with Lynparza capsules (50 mg) on a milligram-to-milligram basis due to differences in the dosing and bioavailability of each formulation. See full PI for Lynparza capsules for specific capsule dosing. Dosage in adults: Lynparza is available as 100 mg and 150 mg tablets. The recommended dose of Lynparza is 300 mg (two 150 mg tablets) taken twice daily, equivalent to a total daily dose of 600 mg. The 100 mg tablet is available for dose reductions only. *Duration of treatment: Maintenance treatment of newly diagnosed advanced ovarian cancer: continue treatment for 2 years or until disease progression. Platinum-sensitive relapsed ovarian cancer and metastatic HER2-negative breast cancer: treatment can be continued until progression of the underlying disease. See full PI. Lynparza tablets can be taken with or without food; they should be swallowed whole and not chewed, dissolved or divided. Dose adjustments: Treatment may be interrupted to manage adverse reactions such as nausea, vomiting, diarrhoea, and anaemia and dose reduction can be considered, see full PI. Co-administration with CYP3A inhibitors: Concomitant use of strong or moderate CYP3A inhibitors is not recommended and alternative agents should be considered. If a strong or moderate CYP3A inhibitor must be co-administered, a dose reduction is recommended, see full PI. Special populations: Patients with moderate renal impairment, the recommended dose of Lynparza is 200 mg twice daily. Lynparza is not recommended in patients with severe renal impairment or end stage renal disease, patients with severe hepatic impairment. Women of childbearing potential: See PRECAUTIONS. For more information, see full PI. CONTRAINDICATIONS: Haematological toxicity is common in patients treated with olaparib and is generally mild-moderate (CTCAE Grade 1 or 2). Grade 3 or higher events of anaemia (decrease in haemoglobin) occurred in 7.4% of patients in Study 19, and one patient died from a haemorrhagic stroke associated with thrombocytopenia. Patients should not start treatment with Lynparza until they have recovered from haematological toxicity or after a washout period. Lynparza treatment should be interrupted and appropriate haematological testing should be initiated. Myelodysplastic syndrome/Acute Myeloid Leukaemia (MDS/AML) has been reported (incidence <1.5% of patients treated in clinical trials with Lynparza monotherapy, including long-term follow-up) and the majority of events had a fatal outcome. All patients had potential contributing factors for the development of MDS/AML. If MDS and/or AML are confirmed while on treatment with Lynparza, it is recommended that LYNPARZA be discontinued and the patient treated appropriately. Use in pregnancy: Category D. Lynparza should not be used during pregnancy due to the teratogenic and genotoxic potential of olaparib. Female partners of male patients taking Lynparza should also avoid pregnancy. Women of childbearing potential should use effective contraception during treatment and for 1 month after receiving the last dose. *Male patients and their female partners of childbearing potential should be advised that they must use effective contraception during treatment and for 3 months after receiving the last dose of Lynparza. For more information, see full PI. Use during lactation: Breast feeding should be avoided in women receiving Lynparza and for 1 month after the last dose. Children or adolescents: Not indicated. Effects on ability to drive and use machinery: Asthma, fatigue, and diziness have been reported and patients and children should observe caution when driving or using machines. INTERACTIONS: Ovarian co-administration with moderate or strong CYP3A inducers or inhibitors is not recommended. Foods that inhibit CYP3A enzymes such as star fruit, grapefruit and Seville oranges should be avoided. Caution when mixed with sensitive CYP3A substrates or substrates with a narrow therapeutic margin. Induction of CYP1A2, 2B6 has been shown in vitro. Inhibition of P-gp, OATP1B1, OCT1, OCT2, DAT, MATE1 and MATE2K has been shown in vitro. Caution should be exercised if LYNPARZA is administered in combination with other therapies that have potential for drug-drug interactions, see full PI. PDR. pediatric uses: Information not available. ADVERSE REACTIONS: Common (≥1% to <10%): anaemia, neutropenia, leukopenia, thrombocytopenia, decreased appetite, diziness, headache, dysgeusia, cough, dyspnoea, vomiting, diarrhoea, nausea, dyspepsia, upper abdominal pain, fatigue. Common (≥1% to <10%): lymphopenia, rash, stomatitis, increase in blood creatinine; for other listed adverse reactions, see full PI. Date of first approval: 23 May 2018 Date of Revision: 21 June 2019.

PBS Information: Lynparza tablets. Authority Required. For maintenance treatment of germline or somatic BRCA mutated platinum-sensitive relapsed high-grade serous ovarian, fallopian tube or primary peritoneal cancer for patients who have responded to prior platinum-based chemotherapy. Prior treatment must have included at least 2 courses of platinum-based regimens. Refer to PBS schedule for full authority information.