Maklumat tambahan indikasi

Tahun 2021

Products Approved For Additional Indication (DCA 357 – 7 Mei 2021)

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Marketing Authorization Holder</th></tr>
<tr><td>1.</td><td>Lynparza 100 mg Film-Coated Tablets [Olaparib 100mg]

Lynparza 150 mg Film-Coated Tablets [Olaparib 150mg]</td><td>
INDICATION :

Lynparza is indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:
• a deleterious or suspected deleterious BRCA mutation, and/or
• genomic instability.

POSOLOGY:
<u>Patient Selection</u>

Select patients for treatment with Lynparza based on the presence of deleterious or suspected deleterious BRCA mutations, or genomic instability based on the indication, biomarker, and sample type (Table 1).

Table 1 Biomarker Testing for Patient Selection
<table>
<tr><th rowspan="2">Indication</th><th rowspan="2">Biomarker</th><th colspan="2">Sample Type</th></tr>
<tr><th>Tumour</th><th>Blood</th></tr>
<tr><td>First-line maintenance treatment of HRD-positive advanced ovarian cancer in combination with bevacizumab*</td><td>BRCA1m, BRCA2m and/or
genomic instability</td><td>X</td><td></td></tr>
</table>
</td><td>ASTRAZENECA SDN. BHD.
Level 11 & 12, Nucleus Tower,
No. 10, Jalan PJU 7/6,
Mutiara Damansara,
47800 Petaling Jaya,
Selangor.</td></tr>
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		** Where testing fails or tissue sample is unavailable/insufficient, or when germline testing is negative, consider using an alternative test.* <u>*Duration of treatment*</u> *First-line maintenance treatment of HRD positive advanced ovarian cancer in combination with bevacizumab:* *Continue Lynparza treatment until disease progression, unacceptable toxicity, or completion of 2 years of treatment. Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider can derive further benefit from continuous Lynparza treatment, can be treated beyond 2 years.* *When used with Lynparza, the recommended dose of bevacizumab is 15 mg/kg every three weeks.* *Bevacizumab should be given for a total of 15 months including the period given with chemotherapy and given as maintenance. Refer to the Prescribing Information for bevacizumab when used in combination with Lynparza for more information.*	

No.	Product [Active Ingredient]	Additional Indication	Marketing Authorization Holder
2.	Imbruvica 140mg Capsules [Ibrutinib 140mg]	**INDICATION :** IMBRUVICA as a single agent or in combination with bendamustine and rituximab (BR) is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor.