Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 380, 5 Januari 2023

Products approved for additional indication (DCA 380 – 5 January 2023)

<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>1.</td><td>Lynparza 100 mg Film-Coated Tablets

Lynparza 150 mg Film-Coated Tablets

[Olaparib 100mg

Olaparib 150mg]</td><td>INDICATION :

Lynparza is indicated for the adjuvant treatment of adult patients with germline BRCA-mutated HER2-negative high risk early breast cancer who have previously been treated with neoadjuvant or adjuvant chemotherapy.

POSOLOGY :

Table 1 Biomarker Testing for Patient Selection

<table>
<tr><td>Indication</td><td>Biomarker</td><td colspan="2">Sample type</td></tr>
<tr><td></td><td></td><td>Tumour</td><td>Blood</td></tr>
<tr><td>Adjuvant treatment of BRCA-mutated HER2-negative high risk early breast cancer</td><td>BRCA1m, BRCA2m</td><td>X</td><td>X</td></tr>
</table>

Adjuvant treatment of BRCA-mutated HER2-negative high risk early breast cancer:

It is recommended that patients are treated for a total of 1 year, or until disease recurrence, whichever occurs first. Patients with hormone receptor-positive breast cancer should continue concurrent treatment with endocrine therapy as per local guidelines.</td><td>ASTRAZENECA SDN. BHD.
Level 11 & 12, The Bousteador,
No. 10, Jalan PJU 7/6,
Mutiara Damansara,
47800 Petaling Jaya,
Selangor.</td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Fraizeron 150mg/ml solution for injection in pre-filled pen Fraizeron 150mg Powder for Solution for Injection Cosentyx 150mg/ml solution for injection in pre-filled syringe [Secukinumab 150mg]	**INDICATION** : <u>Juvenile idiopathic arthritis (JIA)</u> Enthesitis-related arthritis (ERA) Fraizeron/Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active enthesitis-related arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy. Juvenile psoriatic arthritis (JPsA) Fraizeron/Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active juvenile psoriatic arthritis in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy **POSOLOGY :** <u>Juvenile idiopathic arthritis (JIA)</u> Enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) The recommended dose is based on body weight (Table 2) and administered by subcutaneous injection at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. Each 75 mg dose is given as one subcutaneous injection of 75 mg. Each 150 mg dose is given as one subcutaneous injection of 150 mg.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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<tr><td></td><td></td><td>Table 2: Recommended dose for juvenile idiopathic arthritis

<table><tr><th>Body weight at time of dosing</th><th>Recommended dose</th></tr><tr><td><50kg</td><td>75mg</td></tr><tr><td>≥50kg</td><td>150mg</td></tr></table>
The 75mg solution for injection supporting the pediatric patients with body weight <50kg is not registered in this country.

The 150 mg and 300mg solution for injection in pre-filled syringe and pen is not indicated for administration to pediatric patients with a weight <50 kg. The 150 mg powder for solution for injection presentation is appropriate for administration to this population</td><td></td></tr>
</table>