Maklumat tambahan indikasi
Year 2020
Products Approved For Additional Indication (DCA 344 – 30 April 2020)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Tecentriq 60mg/ml concentrate for solution for infusion** [Atezolizumab 60mg/ml]	➢ Indication: <u>*Small cell lung cancer*</u> *Tecentriq, in combination with carboplatin and etoposide, is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).* ➢ Posology: <u>1L ES-SCLC</u> *Tecentriq in combination with carboplatin and etoposide* *During the induction phase, the recommended dose of Tecentriq is 1200 mg administered by IV infusion followed by carboplatin, and then etoposide administered by IV infusion on day 1. Etoposide is also administered by IV infusion on days 2 and 3. This regimen is administered every 3 weeks for four cycles.* *The induction phase is followed by a maintenance phase without chemotherapy in which 1200 mg Tecentriq is administered by IV infusion every 3 weeks.*	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.
2.	2.1 **Tecentriq 60mg/ml concentrate for solution for infusion** [Atezolizumab 60mg/ml]	➢ Indication: <u>*Triple-negative breast cancer (TNBC)*</u> *Tecentriq, in combination with nab-paclitaxel, is indicated for the treatment of patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression ≥1%, and who have not received prior chemotherapy for metastatic disease.*	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.

		➢ Posology: *Do not co-administer other medicinal products through the same infusion line.* *<u>Tecentriq combination therapy</u>* *1L TNBC* *<u>Tecentriq in combination with nab-paclitaxel</u>* *The recommended dose of Tecentriq is 840 mg administered by IV infusion, followed by 100 mg/m2 nab-paclitaxel. For each 28-day cycle Tecentriq is administered on days 1 and 15, and nab-paclitaxel is administered on days 1, 8 and 15. Patients should be selected for treatment based on the tumor expression of PD-L1 confirmed by a validated test* *<u>1L TNBC</u>* *Patients are treated with Tecentriq until disease progression or unacceptable toxicity.*	
3.	3.1 **Cyramza 500mg/50ml concentrate for solution for infusion** [Ramucirumab 10mg/ml] 3.2 **Cyramza 100mg/10ml concentrate for solution for infusion** [Ramucirumab 10mg/ml]	➢ Indication: *<u>Hepatocellular carcinoma</u>* *Cyramza monotherapy is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma who have a serum alpha fetoprotein (AFP) of ≥ 400ng/ml and who have been previously treated with sorafenib.* ➢ Posology: *Hepatocellular carcinoma (HCC)* *The recommended dose of ramucirumab as a single agent is 8 mg/kg every 2 weeks.* *Alpha fetoprotein (AFP) testing in HCC* *Patients with HCC should be selected based on a serum AFP concentration of ≥ 400 ng/ml with a validated AFP test prior to ramucirumab treatment.*	**ZUELLIG PHARMA SDN BHD** No. 15, Persiaran Pasak Bumi, Sek. U8, Perindustrian Bukit Jelutong 40150 Shah Alam, Selangor

4.	4.1 **Xtandi 40mg Soft Capsules** [Enzalutamide 40mg]	➢ Indication: *XYTANDI is indicated for the treatment of adult men with high-risk non-metastatic castration-resistant prostate cancer (CRPC).*	**ASTELLAS PHARMA MALAYSIA SDN BHD** Suite 18.05, Level 18 Centrepoint North Tower Mid Valley City, Lingkaran Syed Putra 59200 Kuala Lumpur
5.	5.1 **Forxiga 5mg Film-Coated Tablet** [Dapagliflozin 5mg] 5.2 **Forxiga 10mg Film-Coated Tablet** [Dapagliflozin 10mg]	➢ Indication: *To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors.*	**ASTRA ZENECA SDN. BHD.** Level 11 & 12 Nucleus Tower, 10 Jalan PJU 7/6, Mutiara Damansara 47800 Petaling Jaya, Selangor