

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 400, 5 September 2024

Products approved for additional indication (DCA 400 – 5 September 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	BRUKINSA 80 mg capsules [Zanubrutinib 80 mg]	<p>INDICATION:</p> <p>BRUKINSA as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL).</p>	<p>BEIGENE MALAYSIA SDN. BHD. Level 13, Menara 1 Sentrum, 201, Jalan Tun Sambanthan, Brickfields, 50470 Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur.</p>
3.	Keytruda 100mg Solution for Infusion [Pembrolizumab 25mg/ml]	<p>INDICATION :</p> <p>Gastric Cancer</p> <p>KEYTRUDA, in combination with fluoropyrimidine and platinum-containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS \geq1.</p> <p>KEYTRUDA, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with CPS \geq1.</p>	<p>MERCK SHARP & DOHME (MALAYSIA) SDN. BHD. Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm No. 1, Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.</p>